				Between text matter to 2D Code t should be min. 3mr		
			Do not print pink colour line. Space for 15 Digit - Sequential 2D Data matrix Barcode shall be printed by the vendor.	Position / Orientation shall b depending upon the Printer's	5	
			Capsules, USP	Mycophenolate Mofetil Mycophenolate Mofetil Mycophenolate Mofetil 40185	Mycophenolate Moretil	
	DOSAGE FORMS AND STRENGTHS Capsules: 250 mg	5.5 Gastrointestinal C	ents, however, reduced immunosuppression may place the gr mplications requiring hospitalization, ulceration and perforations were ob		voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: of • <u>Embryo-Fetal Toxicity</u> : Congenital malformations and spontaneous abortions, mainly in the first trimester, have been reported following	MEDICATION GOIDE
MYCOPHENOLATE MOFETIL CAPSULES and MYCOPHENOLATE MOFETIL TABLETS safely and effectively. See full prescribing information for MYCOPHENOLATE MOFETIL CAPSULES and	Tablets: 500 mg CONTRAINDICATIONS Hypersensitivity to mycophenolate mofetil, MPA acid or any	these serious adverse eff 5.6 Patients with Hypo	requiring nospitalization, uiceration and perforations were oo sets particularly when administering mycophenolate mofetil to xanthine-Guanine Phosphoribosyl-Transferase Deficiency ((an inosine monophosphate dehydrogenase (IMPDH) inhibitor;	patients with a gastrointestinal disease. HGPRT)	exposure to mycophenolate mofetil (MMF) in combination with other immunosuppressants during pregnancy [see Warnings and Precautions (5.1), and Use in Specific Populations (8.1), (8.3)]. Congenital malformations include: - Facial malformations: cleft lip, cleft palate, micrognathia, hypertelorism of the orbits	Mycophenolate Mofetil Tablets, USP
MYCOPHENOLATE MOFETIL TABLETS. MYCOPHENOLATE MOFETIL capsules, for oral use MYCOPHENOLATE MOFETIL tablets, for oral use	component of the drug product (4) WARNINGS AND PRECAUTIONS Blood Dyscrasias (Neutropenia, Red Blood Cell Aplasia):	deficiencies of hypoxanth it may cause an exacerba	ne-guanine phosphoribosyl-transferase (HGPR1) such as Le tion of disease symptoms characterized by the overproduction as acute arthritis, tophi, nephrolithiasis or urolithiasis and re	sch-Nyhan and Kelley-Seegmiller syndromes becai on and accumulation of uric acid leading to sympto	 Antornanics of the fances: only activity is an ormally formed to assert external/induce cal, colobornal, microphilalinos Malformations of the finance: only activity is an ormality in a color activity is activity in a color activity is an ormal of the finance in a color of the f	(mye'' koe fen' oh late moe' fe til) Read the Medication Guide that comes with mycophenolate mofetil tablets and
Initial U.S. Approval: 1995 WARNING: EMBRYOFETAL TOXICITY, MALIGNANCIES AND	Monitor with blood tests; consider treatment interruption or dose reduction. (5.4) • Gastrointestinal Complications: Monitor for complications such as bloeding, ulceration and perforations, particularly	rubella, oral polio, BCG,	cophenolate mofetil, the use of live attenuated vaccines should yellow fever, varicella, and TY21a typhoid vaccines) and pati	ents should be advised that vaccinations may be l	ps, - Nervous system malformations: such as spina bifida.	capsules before you start taking it and each time you refill your prescription. There may be new information. This Medication Guide does not take the place of talking
SERIOUS INFECTIÓNS See full prescribing information for complete boxed warning • Use during pregnancy is associated with increased	such as bleeding, ulceration and perforations, particularly in patients with underlying gastrointestinal disorders. (5.5) Hypoxanthine-Guanine Phosphoribosyl-Transferase Deficiency: Avoid use of mycophenolate moteful. (5.6)	effective. Advise patients 5.10 Blood Donation	to discuss with the physician before seeking any immunizatio e blood during therapy and for at least 6 weeks following disco	ns.	Digestive: Colitis, pancreatitis. Hematologic and Lymphatic: Bone marrow failure, cases of pure red cell aplasia (PRCA) and hypogammaglobulinemia have been	
risks of first trimester pregnancy loss and congenital malformations. Avoid if safer treatment options are available. Females of reproductive potential must be	 Immunizations: Avoid live attenuated vaccines. (5.7) Blood Donation: Avoid during therapy and for 6 weeks 	or blood products might l 5.11 Semen Donation	e administered to a female of reproductive potential or a preg	nant woman.	Precautions (5.4).	Mycophenolate mofetil can cause serious side effects, including:
counseled regarding pregnancy prevention and planning [see Warnings and Precautions (5.1)]. • Increased risk of development of lymphoma and other	thereafter. (5.10) • Semen Donation: Avoid during therapy and for 90 days thereafter. (5.11) • Potential Impairment on Driving and Use of Machinery:	Use In Specific Population	en should not donate semen during therapy and for 90 days for 15 (8.3)]. ant Medications on Mycophenolic Acid Concentrations	ollowing discontinuation of mycophenolate mofetil [Intertions: Hypersensitivity, hypogarininagioonerina. Intections: Meningitis, infectious endocarditis, tuberculosis, atypical mycobacterial infection, progressive multifocal leukoencephalopathy, BK virus infection, viral reactivation of hepatitis B and hepatitis C, protozoal infections [see Warnings and Precautions (5.3)]. 	defects. Females who take mycophenolate motetil during pregnancy have a higher
 malignancies, particularly of the skin [see Warnings and Precautions (5.2)]. Increased susceptibility to infections, including 	Mycophenolate Mofetil may affect ability to drive or operate machinery. (5.13)	A variety of drugs have p of MPA concentrations i	tential to alter systemic MPA exposure when co-administered plasma before and after making any changes to immuno may be appropriate to ensure MPA concentrations remain st	suppressive therapy, or when adding or discontinu		
opportunistic infections and severe infections with fatal outcomes [see Warnings and Precautions (5.3)].		5.13 Potential Impairme Mycophenolate mofetil m	ent of Ability to Drive or Operate Machinery ay impact the ability to drive and use machines. Patients sho	uld avoid driving or using machines if they experie	Vascular: Lymphocele	• If you are a female who can become pregnant, your doctor must talk with you about acceptable birth control methods (contraceptive counseling) to use while
Warnings and Precautions (5.12, 5.13) 2/2019	is evidence of a higher frequency of certain types of infections e.g., opportunistic infection. (6.1)	6 ADVERSE REACTION	zziness, tremor, or hypotension during treatment with mycophen INS ctions are discussed in greater detail in other sections of the l		 7.1 Effect of Other Drugs on Mycophenolate Mofetil Table 5. Drug Interactions with Mycophenolate Mofetil that Affect Mycophenolic Acid (MPA) Exposure 	taking mycophenolate mofetil. You should have 1 pregnancy test immediately before starting mycophenolate mofetil and another pregnancy test 8 to 10 days
Mycophenolate mofetil is an antimetabolite immunosuppressant	To report SUSPECTED ADVERSE REACTIONS, contact Strides Pharma Inc. at 1-877-244-9825 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.com	 Embryofetal Toxicit Lymphomas and O 	/ [see Warnings and Precautions (5.1)] her Malignancies [see Warnings and Precautions 5.2)] see Warnings and Precautions (5.3)]		Antacids with Magnesium or Aluminum Hydroxide Concomitant use with an antacid containing magnesium or aluminum hydroxide decreases MPA	later. Pregnancy tests should be repeated during routine follow-up visits with
	DRUG INTERACTIONS See FPI for drugs that may interfere with systemic exposure and reduce mycophenolate mofetil efficacy: antacids with		Veutropenia, Pure Red Cell Aplasia [see Warnings and Precau nplications [see Warnings and Precautions (5.5)]	tions (5.4)]	Clinical Impact systemic exposure [see Clinical Pharmacology (12.3)], which may reduce mycophenolate mofetil efficacy.	your doctor. Talk to your doctor about the results of all of your pregnancy tests. You must use acceptable birth control during your entire mycophenolate mofetil
ADULTS DOSING	magnesium or aluminum hydroxide, proton pump inhibitors, drugs that interfere with enterohepatic recirculation, telmisartan, calcium-free phosphate binders. (7.1)	Because clinical trials are directly compared to rate	conducted under widely varying conditions, adverse reaction in the clinical trials of another drug and may not reflect the ra 7 patients received mycophenolate mofetil during pivotal clin	ites observed in practice.		treatment and for 6 weeks after stopping mycophenolate mofetil, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely.
Kidney Transplant 1 g twice daily, orally over no less than 2 h (2.2)	 Mycophenolate mofetil may reduce effectiveness of oral contraceptives. Use of additional barrier contraceptive methods is recommended. (7.2) 	these, 991 were included in all study arms also rec	in the three renal studies, 277 were included in one hepatic stu eived cyclosporine and corticosteroids.	dy, and 289 were included in one cardiac study. Patie	nts Clinical Impact Concomitant use with PPIs decreases MPA systemic exposure [see Clinical Pharmacology (12.3)], which may reduce mycophenolate motetil efficacy.	Mycophenolate mofetil decreases blood levels of the hormones in birth control pills that you take by mouth. Birth control pills may not work as well while you
Heart Transplant 1.5 g twice daily orally over no less than 2 h (2.3) Liver Transplant 1.5 g twice daily orally over no less	See FPI for other important drug interactions. (7) USE IN SPECIFIC POPULATIONS	novo kidney (3) heart (1)	primarily derive from five randomized, active-controlled double and liver (1) transplant patients [see Clinical Studies (14.1, 1)]		de Prevention or Management Monitor patients for alterations in efficacy when PPIs are co- administered with mycophenolate mofetil. Examples Lansoprazole, pantoprazole	take mycophenolate mofetil, and you could become pregnant. If you take birth
Liver Transplant 1.3 g twice daily orally over no less than 2 h (2.4) PEDIATRICS	 Pediatric Use: Safety and effectiveness in allogenic heart or livertransplants has not been established (8.4) Male Patients: Sexually active male patients and/or their 	prevention of rejection in	at e reactions for Mycophenolate mofetil was determined in fiv idney, heart and liver transplant patients (two active- and one respectively) <i>[see Clinical Studies (14.1, 14.2 and 14.3)]</i> .		the Drugs that Interfere with Enterohepatic Recirculation	control pills while using mycophenolate mofetil you must also use another form of birth control. Talk to your doctor about other birth control methods that you
Kidney Transplant 600 mg/m² orally twice daily, up to maximum of 2 g daily (2.2)	female partners are recommended to use effective contraception during treatment of the male patient and for at least 90 days after cessation of treatment (8.3)	The three <i>de novo</i> kidney g twice daily) with azath	studies with 12-month duration compared two dose levels oprine (2 studies) or placebo (1 study) when administered it acute rejection episodes. One study also included anti-thyme	n combination with cyclosporine (Sandimmune®) a	f.5 Clinical Impact with enterohepatic recirculation by altering the gastrointestinal flora, can decrease MPA systemic exposure [see Clinical Pharmacology (12.3)], which may reduce mycophenolate mofetil efficacy.	 can use while taking mycophenolate mofetil. If you are a sexually active male whose female partner can become pregnant
 Reduce or interrupt dosing in the event of neutropenia. (2.5) See full prescribing information (FPI) for: adjustments for renal impairment and neutropenia (2.5). 	See 17 for PATIENT COUNSELING INFORMATION and Medication Guide	In the <i>de novo</i> heart tran azathioprine 1.5 to 3 mg,	splantation study with 12-month duration, patients received kg/day (n=289), in combination with cyclosporine (Sandimr	mycophenolate mofetil 1.5 g twice daily (n=289)	ICC	while you are taking mycophenolate mofetil, use effective contraception during treatment and for at least 90 days after stopping mycophenolate mofetil.
· · · · · ·	Revised: 01/2020		py. Iantation study with 12-month duration, patients received my ycophenolate mofetil 1.5 g twice daily orally or azathioprine 1		up aminoglycoside, cephalosporin, fluoroquinolone and penicillin classes of antimicrobials	 If you plan to become pregnant, talk with your doctor. Your doctor will decide if other medicines to prevent rejection may be right for you.
FULL PRESCRIBING INFORMATION: CONTENTS * Warning: Embryofetal Toxicity, Malignancies, and Serious infections 1 Indications and Usage	 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy 8.2 Lactation 8.3 Females and Males of Reproductive Potential 8.4 Pediatric Use 	1 to 2 mg/kg/day orally, in number of patients enroll Approximately 53% of the	combination with cyclosporine (Neoral®) and corticosteroids	as maintenance immunosuppressive therapy. The to ts, and 48% of the liver transplant patients were trea	tal Clinical Impact Concomitant use with drugs inducing glucuronidation decreases MPA systemic exposure, potentially reducing mycophenolate mofetil efficacy, while use with drugs inhibiting glucuronidation increases MPA systemic exposure [see Clinical Pharmacology (12.3)], which may increase the risk of	 If you become pregnant while taking mycophenolate mofetil, do not stop taking mycophenolate mofetil. Call your doctor right away. You and your doctor may
2 DOSAGE AND ADMINISTRATION 2.1 Important Administration Instructions 2.2 Dosing for Kidney Transplant Patients: Adults and	 8.5 Geriatric Use 8.6 Patients with Renal Impairment 8.7 Patients with Hepatic Impairment 	safety data of three kidne	γ transplantation studies are pooled together. ns in Controlled Studies of De Novo Kidney, Heart or Liver		he Prevention or Management Monitor patients for alterations in efficacy or mycophenolate mofetil related adverse reactions when these drugs are co-administered with mycophenolate mofetil.	decide that other medicines to prevent rejection may be right for you. You and your doctor should report your pregnancy to the Mycophenolate Pregnancy
Pediatrics 2.3 Dosing for Heart Transplant Patients: Adults	10 OVERDOSAGE 11 DESCRIPTION		Kidney Studies Hea	rt Study Liver Study	Examples Telmisartan (induces glucuronidation); isavuconazole (inhibits glucuronidation). Calcium Free Phosphate Binders	Registry either: o By phone at 1-800-617-8191 or
2.4 Dosing for Liver transplant Patients: Addits2.5 Dosing Adjustments: Patients with Renal Impairment, Neutropenia		Adverse drug reaction	Mycophenolate mofetil 2g/day (n=501) 100 to 150 Myco- pheno- Placebo late mofetil 2g/day	AZA 1.5 to 3 Mycophenolate AZA 1 to mg/kg/day mofetil 3g/day 2 mg/kg/day	Clinical Impact Concomitant use with calcium free phosphate binders decrease MPA systemic exposure [see Clinical Pharmacology (12.3)], which may reduce mycophenolate mofetil efficacy. Provention or Management Administry calcium free phosphate binders at least 2 hours after mycophenolate mofetil	o By visiting the REMS website at: www.mycophenolateREMS.com The purpose of this registry is to gather information about the health of you and your
	12.3 Pharmacokínetics 13 NONCLINICAL TOXICOLOGY	(MedDRA) System Organ Class	(n=301) or 3g/day (n=490) 100 to 150 mg/day mofetil 3g/day (n=991) (n=326) (n=166) (n=289)		Prevention or Management Administer calcium free phosphate binders at least 2 hours after mycophenolate mofetil. Examples Sevelamer	baby.
5.2 Lymphoma and other malignancies	13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility CLINICAL STUDIES 14.1 Kidney Transplantation	Infections and infestation	% % %	(II-203) (II-207) % %	7.2 Effect of Mycophenolate Motetil on Other Drugs Table 6. Drug Interactions with Mycophenolate Motetil that Affect Other Drugs	Increased risk of getting certain cancers. People who take mycophenolate mofetil have a higher risk of getting lymphoma, and other cancers, especially skin cancer.
 5.3 Serious Infections 5.4 Blood Dyscrasias: Neutropenia and Pure Red Cell Aplasia (PRCA) 	14.2 Heart Transplantation 14.3 Liver Transplantation	Bacterial infections	39.9 33.7 37.3 -	- 27.4 26.5	Drugs that Undergo Renal Tubular Secretion	Tell your doctor if you have:
	15 REFERENCES 16 HOW SUPPLIED/STORAGE AND HANDLING 10.1 Unadian and Diseased	Viral infections Blood and lymphatic sy	- a - 31.1	24.9	Clinical Impact When concomitantly used with mycophenolate mofetil, its metabolite MPAG, may compete with drugs eliminated by renal tubular secretion which may increase plasma concentrations and/or adverse reactions associated with these drugs.	 unexplained fever, prolonged tiredness, a change in the size and color of a mole
5.10 Blood Donation 5.11 Semen Donation	16.1 Handling and Disposal 16.2 Mycophenolate Mofetil capsules 250 mg 16.3 Mycophenolate Mofetil tablets 500 mg	Anemia Ecchymosis	20.0 23.6 2.4 45.0 - - - 20.1	47.1 43.0 53.0 9.7 - -	Prevention or Management Monitor for drug-related adverse reactions in patients with renal impairment. Examples Acyclovir, ganciclovir, probenecid, valacyclovir, valganciclovir	 a brown or black skin lesion with uneven a new skin lesion or bump
5.12 Effect of Concomitant Medications on Mycophenolic Acid Concentrations	17 PATIENT COUNSELING INFORMATION 17.1 Embryofetal Toxicity	Leukocytosis Leukopenia	- - 42.6 28.6 24.8 4.2 34.3	37.4 22.4 21.3 43.3 45.8 39.0	Combination Oral Contraceptives	borders, or one part of the lesion does not • any other changes to your health look like the other
5.13 Potential Impairment of Ability to Drive or Operate Machinery	17.2 Development of Lymphoma and Other Malignancies17.3 Increased Risk of Serious Infections	Leukopenia Thrombocytopenia	<u> 24.2</u>		Concomitant use with mycophenolate mofetil decreased the systemic exposure to levonorgestrel, but did not affect the systemic exposure to ethinylestradiol [see Clinical Pharmacology (12.3)],	

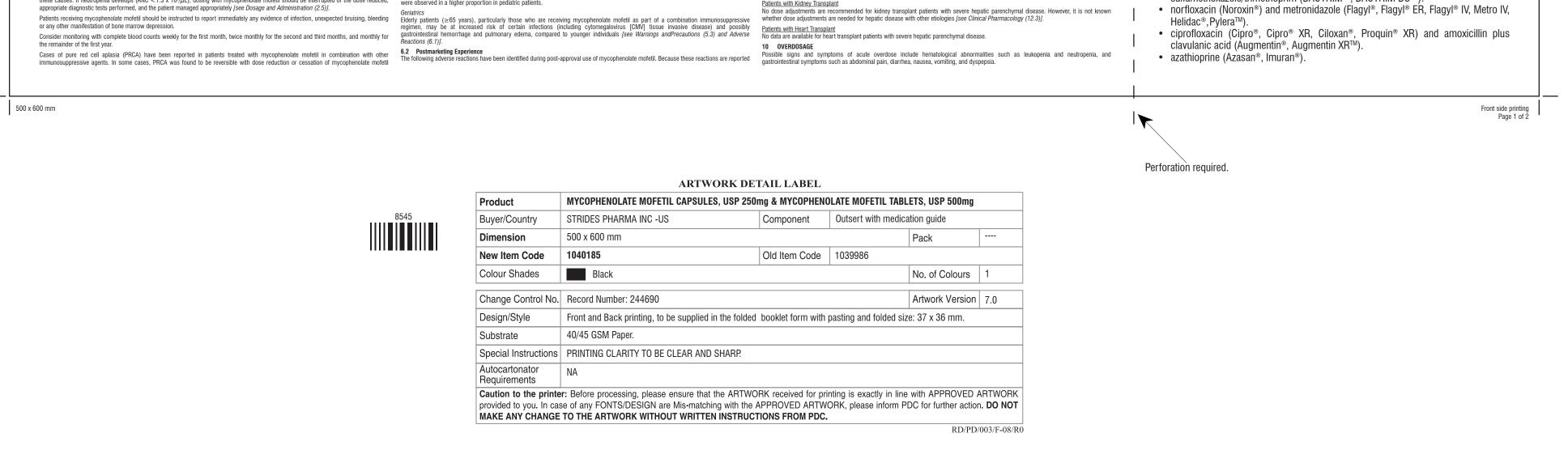
Machinery ADVERSE REACTIONS	17.3 Increased Risk of Serious Infections 17.4 Blood Dyscrasias	Thrombocytopenia		-	-	24.2	28.0	38.3	42.2		t did not affect the systemic exposure ich may result in reduced combination of		
6.1 Clinical Study Experience 6.2 Postmarketing Experience	17.5 Gastrointestinal Tract Complications 17.6 Immunizations	Metabolism and nutritio	n disorders			46.0	43.9			Prevention or Management Use	e additional barrier contraceptive method	ls.	•
DRUG INTERACTIONS	17.7 Administration Instructions 17.8 Blood Donation	Hyperglycemia	-	-	-	48.4	53.3	43.7	48.8	8 USE IN SPECIFIC POPULATIONS			
7.1 Effect of Other Drugs on Mycophenolate Mofetil 7.2 Effect of Mycophenolate Mofetil on Other Drugs		Hyperkalemia	-	-	-	-	-	22.0	23.7	8.1 Pregnancy Pregnancy Exposure Registry			
	*Sections or subsections omitted from the full prescribing.	Hypocalcemia	-	-	-	-	-	30.0	30.0	There is a pregnancy exposure registry t			osed to mycophenolate during pregnancy
	information are not listed	Hypokalemia	-	-	-	32.5	26.3	37.2	41.1	about the registry, visit www.mycophenola		eur treatmen	t. To report a pregnancy or obtain inform
JLL PRESCRIBING INFORMATION		Hypomagnesemia		-	-	20.1	14.2	39.0	37.6	Risk Summary	when any second is appreciated with a		sials of first triangular annual land on
VARNING: EMBRYOFETAL TOXICITY, MALIGNANCIES and S • Use during pregnancy is associated with incre	SERIOUS INFECTIONS eased risks of first trimester pregnancy loss and congenital malformations.	Psychiatric disorders Depression				20.1	15.2		-	increased risk of multiple congenital mal	Iformations in multiple organ systems	[see Humai	risk of first trimester pregnancy loss an n Data]. Oral administration of mycophen
	Females of reproductive potential must be counseled regarding pregnancy autions (5.1). Use in Special Populations (8.1, 8.3)1.	Insomnia			-	43.3	39.8	52.3	47.0				ons and pregnancy loss at doses less and heart transplant patients) <i>[see Animal D</i>
Increased risk of development of lymphoma and of	ther malignancies, particularly of the skin [see Warnings and Precautions (5.2)].	Nervous system disorde	ers			10.0	00.0	02.0	11.0	(,	nd benefits of mycophenolate mofetil shou
Increased susceptibility to bacterial, viral, fungal of henatitis B and C, which may lead to hospitaliz	and protozoal infections, including opportunistic infections and viral reactivation ations and fatal outcomes <i>(see Warnings and Precautions (5.3))</i> .	Dizziness	-	-	-	34.3	33.9	-	-	discussed with the pregnant woman.		-	
INDICATIONS AND USAGE		Headache	-	-	-	58.5	55.4	53.8	49.1				transplant populations is not clear. In the linically recognized pregnancies is 2 to 4%
cophenolate mofetil (MMF) is indicated for the prophyla	axis of organ rejection, in recipients of allogeneic kidney [see Clinical Studies (14.1)],	Tremor	-	-	-	26.3	25.6	33.9	35.5	15 to 20%, respectively.		ournago in c	
	e Clinical Studies (14.3)], in combination with other immunosuppressants.	Cardiac disorders			-,,					<u>Data</u> Human Data			
DOSAGE AND ADMINISTRATION Important Administration Instructions		Tachycardia		-	-	22.8	21.8	22.0	15.7	A spectrum of congenital malformations			ewborns) has been reported in 23 to 27
	supervision of a physician with experience in immunosuppressive therapy.	Vascular disorders	07.5	00.0	100	70.0	74.0	00.4	50.0				es. Malformations that have been docume nomalies of the distal limbs, heart, esopha
cophenolate Mofetil Capsules and Tablets cophenolate mofetil oral dosage forms (capsules, table	ets) should not be used interchangeably with mycophenolic acid delayed-release	Hypertension Hypotension	27.5	32.2	19.3	78.9 34.3	74.0 40.1	62.1	- 59.6	kidney, and nervous system.			
lets without supervision of a physician with experie	ence in immunosuppressive therapy because the rates of absorption following the is and mycophenolic acid delayed-release tablets are not equivalent.		nd mediastinal dis	sorders		04.0	40.1			Based on published data from pregnancy MMF exposure.	y registries, the risk of first trimester p	pregnancy lo	oss has been reported at 45 to 49% follo
, ,	is and mycophenolic actu delayed-release tablets are not equivalent. I mycophenolate mofetil capsules should not be opened or crushed. Patients should		-	-	-	40.5	32.2		-	Animal Data			
id inhalation or contact of the skin or mucous membra	anes with the powder contained in mycophenolate mofetil capsules. If such contact		-	-	-	44.3	44.3	31.0	30.3	In animal reproductive toxicology studies toxicity. Oral administration of MMF to pr			
	th soap and water. In case of ocular contact, rinse eyes with plain water.	Pleural effusion	-	-	-	-	-	34.3	35.9	malformations including anophthalmia, ag	gnathia, and hydrocephaly at doses eq	uivalent to (0.03 and 0.02 times the recommended hi
mycophenolate mofetil be administered on an empt	iven as soon as possible following kidney, heart or liver transplant. It is recommended ty stomach. In stable transplant patients, however, mycophenolate mofetil may be		ers		'		·			doses for renal and cardiac transplant pa Gestational Day 7 to Day 19 produced i	increased embryofetal lethality and feta	al malformat	tions included ectopia cordis, ectopic kid
ninistered with food if necessary [see Clinical Pharmac ents should be instructed to take a missed dose as soo	cology (12.3)]. on as they remember, except if it is closer than 2 hours to the next scheduled dose; in	Abdominal pain	22.4	23.0	11.4	41.9	39.4	62.5	51.2		nia at dose equivalents as low as 0.1		nes the recommended human doses for
case, they should continue to take mycophenolate mo		Constipation	-	-	-	43.6	38.8	37.9	38.3	8.2 Lactation			
Dosing for Kidney Transplant Patients: Adults and	Pediatrics	Decreased appetite	-	-	-	-	-	25.3	17.1	Risk Summary	conhanalata in human mille as the effect	te on miller	roduction. There are limited data in the M
	is 1 g orally or intravenously infused over no less than 2 hours, twice daily (daily dose	Diarrhea	30.4	20.9	13.9	52.6	39.4	51.3	49.8	There are no data on the presence of myo Transplantation Pregnancy Registry on the	e effects of mycophenolate on a breast	fed child [se	e Data]. Studies in rats treated with MMF
g).		Dyspepsia	-	-	-	22.1	22.1	22.4	20.9	shown mycophenolic acid (MPA) to be pr breastfeeding infant.	resent in milk. Because available data	are limited, i	it is not possible to exclude potential risk
<u>atrics (3 months and older)</u> atric dosing is based on body surface area (BS/	A). The recommended dose of mycophenolate mofetil for oral suspension for	Nausea Vomiting	-		-	56.1 39.1	60.2 34.6	54.5 32.9	51.2 33.4	The developmental and health benefits of t	breastfeeding should be considered alor	ig with the n	nother's clinical need for myconhenolate
atric kidney transplant patients 3 months and ol	der is 600 mg/m ² , administered twice daily (maximum daily dose of 2g or		 3	-	1 -	ວອ.1	04.0	32.3	33.4	and any potential adverse effects on the br			
IL of the oral suspension). Pediatric patients with BSA e 1. Pediatric Dosing Using Capsules or Tablets for	A ≥ 1.25 m ² may be dosed with capsules or tablets as follows:	Blood lactate	T				Г			<u>Data</u> Limited information is available from the Na	ational Transplantation Programmy Poolo	try Of cover	infants reported by the National Transpla
dy Surface Area Dosing		dehydrogenase increased	-	-	-	23.5	18.3	-	-	Pregnancy Registry to have been breastfed	d while the mother was taking mycopher		
· · · · · ·	capsule 750 mg twice daily (1.5 g daily dose)	·	+					24.9	19.2	for up to 14 months. No adverse events we	•		
	capsules or tablets 1 g twice daily (2 g daily doce)	Hepatic enzyme increased	-	-	-	-	-	24.9	19.2	8.3 Females and Males of Reproductiv Females of reproductive potential must be		irst trimeste	r pregnancy loss and congenital malform
Dosing for Heart Transplant Patients: Adults		Skin and subcutaneous	tissues disorders	1						and must be counseled regarding pregnan	icy prevention and planning.		
ecommended dose of mycophenolate mofetil for adu	It heart transplant patients is 1.5 g orally.	Rash		-	-	26.0	20.8	-	-	<u>Pregnancy Planning</u> For patients who are considering pregnan	ncy, consider alternative immunosuppre	ssants with	less potential for embryofetal toxicity wh
Dosing for Liver Transplant Patients: Adults	It liver transplant patients is 1.5 a administered erally twice daily (daily does of 2 a)	Renal and urinary disor	ders							possible. Risks and benefits of mycopheno	olate mofetil should be discussed with t	ne patient.	
Dosing Adjustments: Patients with Renal Impairm	It liver transplant patients is 1.5 g administered orally twice daily (daily dose of 3 g).	Blood creatinine increased	-	-	-	42.2	39.8	-	-	Pregnancy Testing To prevent unplanned exposure during pre	eonancy, all females of reproductive po	tential shoul	d have a serum or urine pregnancy test
al Impairment		Blood urea increased	-	-	-	36.7	34.3	-	-	sensitivity of at least 25 mIU/mL immediat	tely before starting mycophenolate mof	etil. Another	pregnancy test with the same sensitivity
	ients with delayed graft function postoperatively [see Clinical Pharmacology (12.3)]. airment of the graft (GFR <25 mL/min/1.73 m²), do not administer doses of		administration site	e conditions					·	be done 8 to 10 days later. Repeat pregnan be discussed with the patient. In the eve			
	e patients should be carefully monitored [see Clinical Pharmacology (12.3)].	Asthenia	-	-	-	49.1	41.2	35.4	33.8	embryofetal toxicity whenever possible.			
tropenia eutropenia develops (ANC <1.3 x 103//J), dosing with	mycophenolate mofetil should be interrupted or reduced, appropriate diagnostic tests	Edema ^b	21.0	28.2	8.4	67.5	55.7	48.4	47.7	Contraception Female Patients			
	rnings and Precautions (5.4) and Adverse Reactions (6.1].	, Pain °	24.8	32.2	9.6	79.2	77.5	74.0	77.5	Females of reproductive potential taking (see Table 7 for acceptable contraception r			
DOSAGE FORMS AND STRENGTHS	the in the full wine descent form and strength.	Pyrexia	-	-	-	56.4	53.6	52.3	56.1	and for 6 weeks after stopping mycophene	olate mofetil, unless the patient chooses	abstinence.	
cophenolate mofetil for tablets and capsules are availat apsules 250 mg mycophenolate mofe	etil, white to off-white blend of mycophenolate mofetil filled in size "1" hard gelatin	a : "-" Indicates that the in b : "Edema" includes peri				nclusion in the	e table.			Patients should be aware that mycopher theoretically reduce its effectiveness /see l		the hormor	nes from the oral contraceptive pill and
	vory Body, printed "SAL" on cap and "726" on body in black.	c : "Pain" includes muscu								Table 7. Acceptable Contraception Metho		ntial	
blets 500 mg mycophenolate mofe on one side and engraved "72	etil, pinkish brown colored, capsule shaped, film coated tablet with "SAL" engraved	In the three <i>de novo</i> kidn receiving 3 g/day of myco			ay of mycophe	ienolate mofe	til had an overall	oetter safety profil	e than did patients	Pick from the following birth control optic	1		
		Post-transplant lymphopr			mphoma) dev	veloped in 0.4	4% to 1% of patie	nts receivina mvc	ophenolate mofetil	Option 1	 Intrauterine devices (IUDs) Tubal sterilization 		
CONTRAINDICATIONS rgic reactions to mycophenolate mofetil have been	observed; therefore, mycophenolate mofetil is contraindicated in patients with a	(2 g or 3 g daily) with c	other immunosupp	pressive agents in	controlled cl	linical trials o			t patients followed	Methods to Use Alone	Patient's partner vasectomy		
5 5 1 (), 5 1		tunos of malignanov in 0	7% to 2 1% of nat	tients. Three-vear	NULL-ILICIATION	ma ekin care			of nationte other				
WARNINGS AND PRECAUTIONS Embryofetal Toxicity	nenolic acid (MPA) or any component of the drug product.					ı kidney and l	inomas occurred heart transplant pa	in 1.6% to 4.2% tients did not reve	eal any unexpected				1
e of MMF during pregnancy is associated with an in		changes in incidence of r post-transplant.				ı kidney and l	inomas occurred heart transplant pa	in 1.6% to 4.2% tients did not reve	eal any unexpected	OR Option 2	Hormone Methods		Barrier Methods
termations, consolably external cost and there is a set	nenolic acid (MPA) or any component of the drug product. creased risk of first trimester pregnancy loss and an increased risk of congenital	changes in incidence of r post-transplant. ^I Cytopenias, including leu	malignancy compa ukopenia, anemia, t	ared to the 1-year thrombocytopenia	data. In pedia a and pancyto	n kidney and h atric patients, openia are a	inomas occurred heart transplant pa , PTLD was obser known risk assoc	in 1.6% to 4.2% tients did not reve ved in 1.35% (2/1 iated with mycop	eal any unexpected 48) by 12 months ohenolate and may		choose 1		choose 1
phagus, kidney and nervous system. Females of reproc	nenolic acid (MPA) or any component of the drug product. creased risk of first trimester pregnancy loss and an increased risk of congenital bnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, ductive potential must be made aware of these risks and must be counseled regarding	changes in incidence of r post-transplant. Cytopenias, including leu lead or contribute to the x 10 ³ /µL) developed in u	malignancy compa ukopenia, anemia, f occurrence of infe	ared to the 1-year thrombocytopenia ections and hemo	data. In pedia a and pancyto rrhages <i>[see</i>	n kidney and h atric patients, openia are a <i>Warnings an</i>	inomas occurred neart transplant pa , PTLD was obser known risk asso nd Precautions (5.	in 1.6% to 4.2% tients did not reve ved in 1.35% (2/1 iated with mycop 3)]. Severe neutro	eal any unexpected 48) by 12 months obenolate and may openia (ANC <0.5	Option 2 Choose One Hormone Method AND	choose 1 Estrogen and Progesterone • Oral Contraceptive Pill	AND	choose 1 Diaphragm with spermicide Cervical cap with spermicide
pphagus, kidney and nervous system. Females of reproc gnancy prevention and planning. Avoid use of MMF duri	nenolic acid (MPA) or any component of the drug product. creased risk of first trimester pregnancy loss and an increased risk of congenital bnormalities including cleft lip and palate, and anomalies of the distal limbs, heart,	 changes in incidence of r post-transplant. Cytopenias, including leu lead or contribute to the x 10³/μL) developed in u patients receiving mycopl 	malignancy compa ukopenia, anemia, occurrence of infe up to 2.0% of kidne vhenolate mofetil 3 g	thrombocytopenia ections and hemo ney transplant pati- g daily [see Warni	data. In pedia a and pancyto rrhages [see ents, up to 2. ings and Prece	a kidney and H atric patients, openia are a <i>Warnings an</i> .8% of heart cautions (5.4)	inomas occurred heart transplant pa PTLD was obser known risk asso d Precautions (5. transplant patient and Dosage and	in 1.6% to 4.2% tients did not reve ved in 1.35% (2/1 iated with mycop 3)]. Severe neutro s and up to 3.6% Administration (2.	eal any unexpected 48) by 12 months obenolate and may openia (ANC <0.5 of liver transplant 5)].	Option 2 Choose One	choose 1 Estrogen and Progesterone	AND	choose 1 • Diaphragm with spermicide
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bhagus, kidney and nervous system. Females of reprod nrancy prevention and planning. Avoid use of MMF duri , 8.3)?. Lymphoma and Other Malignancies ents receiving immunosuppressants, including mycoph	henolic acid (MPA) or any component of the drug product. creased risk of first trimester pregnancy loss and an increased risk of congenital bnormalifies including cleft lip and palate, and anomalies of the distal limbs, heart, ductive potential must be made aware of these risks and must be counseled regarding ing pregnancy if safer treatment options are available <i>[see Use in Specific Populations</i> henolate mofetil, are at increased risk of developing lymphomas and other malignancies,	changes in incidence of r post-transplant. Cytopenias, including leu lead or contribute to the x 10 ³ /µL) developed in u patients receiving mycopl The most common oppor candida, GMV viremia/syn mycophenolate mofetti (2	malignancy compa ukopenia, anemia, occurrence of infe up to 2.0% of kida henolate mofetil a rtunistic infections i rndrome, and herpes (2 g or 3 g) in com	ared to the 1-year thrombocytopenia ections and hemo ney transplant patii g daily [see Warni in patients receivil s simplex. The pro- ntrolled studies for	data. In pedia a and pancyto rrhages [see ents, up to 2. ings and Preca ng mycophem oportion of pai r prevention o	h kidney and h atric patients, openia are a <i>Warnings an</i> .8% of heart cautions (5.4) holate mofetil atients with Cl of kidney, hea	inomas occurred neart transplant pp PTLD was obser known risk assound Precautions (5. transplant patient and Dosage and with other immun MV viremia/syndro art or liver rejection	in 1.6% to 4.2% titents did not reve ved in 1.35% (2/1 iated with mycop 3)]. Severe neutro s and up to 3.6% Administration (2. osuppressants we me was 13.5%. Ir n, fatal infection/	eal any unexpected 48) by 12 months openia (ANC <0.5 of liver transplant 5)]. re mucocutaneous n patients receiving	Option 2 Choose One Hormone Method <i>AND</i> One Barrier Method	choose 1 Estrogen and Progesterone Oral Contraceptive Pill Transdermal patch Vaginal ring Progesterone-only Injection	AND	choose 1 Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge
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Biood Dyscrasias: Neutropenia and Pure Red Cell ere neutropenia [absolute neutrophil count (ANC) < CC)	henolic acid (MPA) or any component of the drug product. creased risk of first trimester pregnancy loss and an increased risk of congenital horomalities including cleft lip and palate, and anomalies of the distal limbs, heart, ductive potential must be made aware of these risks and must be counseled regarding ing pregnancy if safer treatment options are available <i>[see Use in Specific Populations</i> , risk appears to be related to the intensity and duration of immunosuppression rather creased risk for skin cancer, exposure to sunlight and UV light should be limited by high protection factor. oped in 0.4% to 1% of patients receiving mycophenolate mofetil (2 g or 3 g) with other icreased risk for skin cancer, exposure to sunlight and UV light should be limited by high protection factor. oped in 0.4% to 1% of patients receiving mycophenolate mofetil (2 g or 3 g) with other icreased risk for skin cancer, exposure to sunlight and UV light should be limited by high protection. The risk of PTLD appears greatest in those individuals who are EBV hildren. In pediatric patients, no other malignancies besides PTLD were observed in unsitic infections. The risk increased risk of developing bacterial, fungal, protozoal unsistic infections. The risk increased risk of developing bacterial, fungal, protozoal institut rangelant patients who receive an organ from a CMV seropositive donor are at B and C develop new infections or reactivate viral infections, weighing the risk that reduced t. with serious outcomes, including deteriorating renal function and renal graft loss <i>[see</i> tect patients at risk for PVAN. th hemiparesis, apathy, confusion, cognitive deficiencies, and ataxia <i>[see Adverse</i> ins should consider PML in the differential diagnosis in patients reporting neurological ng transplant recipients seronegative for CMV at time of transplant who receive a graff o limiting CMV disease exist and should be routinely provided. Patient monitoring may th HBV or HCV. Monitoring infected patients for clinical	changes in incidence of r post-transplant. Cytopenias, including leu lead or contribute to the x 10 ⁵ /µL) developed in u patients receiving mycoph The most common oppor candida, CMV viremia/syn mycophenolate mofetil (2 approximately 2% of kidn The most serious gastroi mofetil. Mouth, esophage hemorrhagic forms of ga disorders were diarrhea, isolated cases of intestil and corticosteroids. 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In pedia a and pancyto rrhages <i>[see</i> ents, up to 2. <i>ings and Preca</i> . oportion of par prevention o ver patients <i>[s</i> zeration and h ulcers often o and Precauti t patients treat o Kidney, Hea closported during roles often o and Precauti t patients treat o Kidney, Hea closporine a ms nernia, malaise rder, ecchymo pathet, ecchymo chucer, gastriti ch ulcer, stom plasm, skin ca sthesia, somn thenia	k kidney and 1 atric patients, openia are a <i>Warnings</i> an <i>Sw</i> of heart <i>sautions</i> (5.4) loolate mofetili titients with Cl of kidney, hear see <i>Warnings</i> see <i>Warnings</i> are noted by a protection of kidney, we see <i>warnings</i> see <i>warnings</i> see <i>warnings</i> are <i>increased</i> , <i>h</i> is, gastrointe: attice arcinoma opence	inomas ⁵ occurred neart transplant pr PTLD was obser known risk assoo do Precautions (5 transplant patient and Dosage and With other immun WV viremia/syndr art or liver rejectio and Precautions clinical trials, while transplantation R eroids	in 1.6% to 4.2% titents did not reverved in 1.35% (2/1 iated with mycop 3). Severe neutro 3). Severe neutro s and up to 3.6% ddministration (2. bsuppressants we we vas 13.5%. Ir n, fatal infection/: (5.3). isks associated well as hematen the most comm well as hematen the most comm well as hematen the most comm apported in 3% to phosphatemia, we hepatitis, ileus, n in 100 pediatric	al any unexpected 48) by 12 months benolate and may openia (ANC <0.5 of liver transplant 5)]. re mucocutaneous n patients receiving sepsis occurred in rith mycophenolate nesis, melena, and ion gastrointestinal i diarrhea revealed vere reported with with cyclosporine <20% of Patients	Option 2 Choose One Hormone Method AND One Barrier Method AND One Barrier Method OR Option 3 Choose One Barrier Method from each column (must choose two methods) Male Patients Genotoxic effects have been observed i 2.5 times. Thus, the risk of genotoxic of patients and/or their female partners ar at least 90 days after cessation of treatm during treatment with mycophenolate mo Nonclinical Toxicology (13.1), Patient Court 8.4 Pediatric Use Safety and effectiveness of mycophenola kidney rejection after allogeneic kidney tra and well-controlled studies of mycopheno of mycophenolate mofetil in pediatric patient Reactions (6.1), Clinical Pharmacology (1 Safety and effectiveness in pediatric patient 8.5 Geriatric Use Clinical studies of mycophenolate mofetil d differently from younger subjects. Other rep patients. In general, dose selection for an elf and of concomitant drug therapies. [see Ad 8.6 Patients with Renal Impairment Patientis with Kidney Transplant No dose adjustments are needed in kidn carefully monitored [see Clinical Pharmaccor min/1.73 m ²), no dose adjustments are ne Patients with Heart and Liver Transplant	choose 1 Estrogen and Progesterone Oral Contraceptive Pill Transdermal patch Vaginal ring Progesterone-only Injection Injection Injent Inaphragm with spermicide Cervical cap with spermicide Cervical cap with spermicide Contraceptive sponge In animal studies at exposures excee effects on sperm cells cannot be exx re recommended to use effective con tent Also, based on the potential risk o feti and for at least 90 days after ces nseling Information (17.9)]. ate mofetil have been established in pe ansplant. 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Base traception of f genotoxic c sation of tree in this popu ata from one transplant <i>f</i> . usplants have bjects aged ed difference. n the presen <i>(7)].</i> ayed graft f s with sever g administer	choose 1 • Diaphragm with spermicide • Cervical cap with spermicide • Contraceptive sponge • Male condom • Female condom • Female condom • Male condom • Female condom • Male condom • Male condom • Male condom • Male condom • Female condom • Ins potential risk, sexually active during treatment of the male patient an effects, male patients should not donate satament <i>[see Use in Special Populations</i> nts 3 months and older for the prophyla: alation is supported by evidence from ade open-label, pharmacokinetic and safety see Dosage and Administration (2.2), Ad e not been established. 65 and over to determine whether they resses in responses between the elderly and yo ce of decreased hepatic, renal or cardiac fur unction postoperatively but patients shou e chronic impairment of the graft (GFR <21 red twice a day should be avoided.
 pophagus, kidney and nervous system. Females of reprocegnancy prevention and planning. Avoid use of MMF duri 1, 8.3)]. 2 lymphoma and Other Malignancies teints receiving immunosuppressants, including mycoph tricularly of the skin /see Adverse Reactions (6.1)]. The nn to the use of any specific agent. For patients with in aring protective clothing and using a sunscreen with a 1 st-transplant lymphoproliferative disorder (PTLD) develot munosuppressive agents in controlled clinical trials of k PTLD cases appear to be related to Epstein Barr Virus ronegative, a population which includes many young clinical trials <i>(see Adverse Reactions (6.1))</i>. Serious Infections tients receiving immunosuppressants, including mycod d new or reactivated viral infections, including opportuctious viral infections reported include: Polyomavirus-associated nephropathy (PVAN), espru JC virus-associated progressive multifocal leukoent Cytomegalovirus (CMV) viremia and CMV disease. 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Patients receiving in served most frequently in the period from 31 to 180 day 	henolic acid (MPA) or any component of the drug product. creased risk of first trimester pregnancy loss and an increased risk of congenital bnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, ductive potential must be made aware of these risks and must be counseled regarding ing pregnancy if safer treatment options are available <i>[see Use in Specific Populations</i> renolate mofetil, are at increased risk of developing lymphomas and other malignancies, risk appears to be related to the intensity and duration of immunosuppression rather creased risk for skin cancer, exposure to sunlight and UV light should be limited by high protection factor. poped in 0.4% to 1% of patients receiving mycophenolate mofetil (2 g or 3 g) with other ichex, heart and liver transplant patients <i>[see Adverse Reactions</i> (6, 1)]. The majority (EBV) infection. The risk of PTLD appears greatest in those individuals who are EBV hildren. In pediatric patients, no other malignancies besides PTLD were observed in pophenolate mofetil, are at increased risk of developing bacterial, fungal, protozoal mistic infections. The risk increases with the total immunosuppressive load. 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Table 4 Adverse Reactio Treated with Mycopheno System Organ Class Body as a Whole Infections and Infestation Hematologic and Lymph- Urogenital Cardiovascular Metabolic and Nutritional Digestive Neoplasm benign, malign unspecified Skin and Appendages Psychiatric Nervous Musculoskeletal <i>Pediatric Study</i> The type and frequency fu to 18 years of age dosec	malignancy compa ukopenia, anemia, i occurrence of infe up to 2.0% of kidm whenolate mofetil 3 og rutnistic infections i ruforme, and herpes 2 g or 3 g) in com tey and heart patien intestinal disorders eal, gastric, duoder astritis and collits w , nausea and vorniti inal villous atrophy in kidney, heart, ar ons in Controlled S olate Mofetil in Com ns natic al upant and of adverse events d with mycophenol	ared to the 1-year thrombocytopenia ections and hemo yey transplant pati- in patients receivi as simplex. The pro- ntrolled studies for throlled studies for perported were ulc nal, and intestinal were commonly re titing. 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Severe neutro s and up to 3.6% Administration (2. Susperessants we we was 13.5%. Ir n, fatal infection/: (5.3)/. isks associated w well as hematen te mofetil -related rerse reactions w il, in combination apported in 3% to phosphatemia, we hepatitis, ileus, n in 100 pediatric the to aily) wer	al any unexpected 48) by 12 months benolate and may openia (ANC <0.5 of liver transplant 5)]. re mucocutaneous n patients receiving sepsis occurred in ith mycophenolate mesis, melena, and ion gastrointestinal diarrhea revealed vith cyclosporine <20% of Patients eight loss ausea and patients 3 months re generally similar	Option 2 Choose One Hormone Method AND One Barrier Method AND One Barrier Method OR Option 3 Choose One Barrier Method from each column (must choose two methods) Male Patients Genotoxic effects have been observed i 2.5 times. 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phagus, kidney and nervous system. Females of reproc grancy prevention and planning. Avoid use of MMF duri 1, 8.3)!. Lymphoma and Other Malignancies ients receiving immunosuppressants, including mycoph ticularly of the skin (see Adverse Reactions (6.1)). The n to the use of any specific agent. For patients with in aring protective clothing and using a sunscreen with a 1 st-transplant lymphoproliferative disorder (PTLD) develor munosuppressive agents in controlled clinical trials of k PTLD cases appear to be related to Epstein Barr Virus onegative, a population which includes many young cl ical trials [see Adverse Reactions (6.1)]. Serious Infections ients receiving immunosuppressants, including mycod d new or reactivated viral infections, including opportu- totical trials (see Adverse Reactions (6.1)]. 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[see Ad 8.6 Patients with Renal Impairment Patients with Kidney Transplant No dose adjustments are needed in kidn carefully monitored [see Clinical Pharmaccom min/1.73 m ²), no dose adjustments are ne Patients with Heart and Liver Transplant No dosta are available for heart or liver trans liver transplant patients with severe chronie	choose 1 Estrogen and Progesterone Oral Contraceptive Pill Transdermal patch Vaginal ring Progesterone-only Injection Injection Injection Diaphragm with spermicide Cervical cap with spermicide Cervical cap with spermicide Contraceptive sponge in animal studies at exposures excee effects on sperm cells cannot be exc re recommended to use effective coi rent. Also, based on the potential risk o fetti and for at least 90 days after ces nseling Information (17.9)]. ate mofetil have been established in pe ansplant. 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 Leukopenia
 28.6
 24.8
 4.2
 34.3
 43.3
 45.8
 39.0

 Thrombocytopenia
 24.2
 28.0
 38.3
 42.2
 Concomitant use with mycophenolate mofetil decreased the systemic exposure to ethinylestradiol [see Clinical Pharmacology (12.3)], which may result in reduced combination oral contraceptive effectiveness.
 X
 Increased risk of getting serious infections. Mycophenolate mofetil weakens the mofetil weakens the mofetil weakens the mofetil weakens in the systemic exposure to ethinylestradion or all contraceptive effectiveness.
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 Increased risk of getting serious infections. Mycophenolate mofetil weakens the mofetil weakens the mofetil weakens the mofetil weakens in the systemic exposure to ethinylestradion or all contraceptive effectiveness.
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 Increased risk of getting serious infections. Mycophenolate mofetil weakens the mofetil we body's immune system and affects your ability to fight infections. Serious infections can happen with mycophenolate mofetil and can lead to hospitalizations and death. These serious infections can include: • Viral infections. Certain viruses can live in your body and cause active infections when your immune system is weak. Viral infections that can happen with mycophenolate mofetil include: • Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections. o BK virus. BK virus can affect how your kidney works and cause your transplanted kidney to fail. • Hepatitis B and C viruses. Hepatitis viruses can affect how your liver works. Talk to your doctor about how hepatitis viruses may affect you. • A brain infection called Progressive Multifocal Leukoencephalopathy (PML). In some patients, mycophenolate mofetil may cause an infection of the brain that may cause death. You are at risk for this brain infection because you have a weakened immune system. Call your doctor right away if you have any of the following symptoms: weakness on one side of the body you are confused or have problems thinking you do not care about things you usually care about (apathy) you cannot control your muscles Fungal infections. Yeasts and other types of fungal infections can happen with mycophenolate mofetil and can cause serious tissue and blood infections (See "What are the possible side effects of mycophenolate mofetil?"). Call your doctor right away if you have any of the following signs and symptoms of infection: temperature of 100.5°F or greater pain during urination cold symptoms, such as a runny nose or sore throat white patches in the mouth or throat • flu symptoms, such as an upset stomach, stomach pain, vomiting or diarrhea unexpected bruising or bleeding earache or headache • cuts, scrapes or incisions that are red, warm and oozing pus See "What are the possible side effects of mycophenolate mofetil?" for information about other serious side effects. What is mycophenolate mofetil? Mycophenolate mofetil is a prescription medicine to prevent rejection (antirejection medicine) in people who have received a kidney, heart or liver transplant. Rejection is when the body's immune system perceives the new organ as a "foreign" threat and attacks it. Mycophenolate mofetil is used with other medicines containing cyclosporine and corticosteroids. Who should not take mycophenolate mofetil? Do not take mycophenolate mofetil if you are allergic to mycophenolate mofetil or any of the ingredients in mycophenolate mofetil capsules and tablets. See the end of this Medication Guide for a complete list of ingredients in mycophenolate mofetil capsules and tablets. What should I tell my doctor before taking mycophenolate mofetil? Tell your doctor about all of your medical conditions, including if you: have any digestive problems, such as ulcers. • have Lesch-Nyhan syndrome, Kelley-Seegmiller syndrome, or another rare inherited deficiency hypoxanthine-guanine phosphoribosyl transferase (HGPRT). You should not take mycophenolate mofetil if you have one of these disorders. • plan to receive any vaccines. People taking mycophenolate mofetil should not receive live vaccines. Some vaccines may not work as well during treatment with mycophenolate mofetil. • are pregnant or plan to become pregnant. See "What is the most important information I should knowabout mycophenolate mofetil?" • are breastfeeding or plan to breastfeed. It is not known if mycophenolate mofetil passes into breast milk. You and your doctor will decide if you will take mycophenolate mofetil or breastfeed. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Some medicines may affect the way mycophenolate mofetil works, and mycophenolate mofetil may affect how some medicines work. Especially tell your doctor if you take: • birth control pills (oral contraceptives). See "What is the most important information I should know about mycophenolate mofetil?" • sevelamer (Renagel[®], Renvela[™]). These products should be taken at least 2 hours after taking mycophenolate mofetil. • acyclovir (Zovirax[®]), valacyclovir (Valtrex[®]), ganciclovir (CYTOVENE[®]-IV, Vitrasert[®]), valganciclovir (VALCYTE®). • rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®]). • antacids that contain magnesium and aluminum (mycophenolate mofetil and the antacid should not be taken at the same time).

proton pump inhibitors (PPIs) (Prevacid[®], Protonix[®]).

• sulfamethoxazole/trimethoprim (BACTRIM[™], BACTRIM DS[™]).



	1														
	T														
 cholestyramine (Questran Light[®], Questran[®], Locholest Light, Locholest, Prevalite[®]). 		The experience with overdose of mycophenolate mofetil in humans is limited. The reported effects associated with overdose fall within the known safety profile of the drug. The highest dose administered to kidney transplant patients in clinical trials has been 4 g/day.						ic Parameters for He	patic Impairment		Pediatrics- De Novo Kidney transplantation PK One open-label safety and pharmacokinetic s		al suspension 600 ma/m² t	twice daily (up to 1 a twic	
Know the medicines you take. Keep a list of them to show to your doctor or nurse	In limited experience with h of 4 g/day or 5 g/day, the	In limited experience with heart and liver transplant patients in clinical trials, the highest doses used were 4 g/day or 5 g/day. At doses of 4 g/day or 5 g/day, there appears to be a higher rate, compared to the use of 3 g/day or less, of gastrointestinal intolerance (nausea, vomiting, and/or diarrhea), and occasional hematologic abnormalities, particularly neutropentia [see Warmings and Precautions					Dose	T _{max (h)}	C _{max (mcg/mL)}	One open-label, safety and pharmacokinetic study of mycophenolate mofetil for oral suspension 600 mg/m ² twice daily (up to 1 g twice daily) in combination with cyclosporine and corticosteroids was performed at centers in the United States (9), Europe (5) and Australia (1) in 100 pediatric patients (3 months to 18 years of age) for the prevention of renal allograft rejection. Mycophenolate mofetil					
and pharmacist when you get a new medicine. Do not take any new medicine without talking with your doctor.	(nausea, vomiting, and/or d (5.4)].	arrhea), and occasiona	hematologic abnormalitie	es, particularly neutropenia [see Warnings and Precautions	Healthy Volunteers	1 g	0.63	24.3	29.0	was well tolerated in pediatric patients [see adult patients dosed with 1 g twice daily my	cophenolate mofetil capsules [see Clin	nical Pharmacology (12.3)	7. The rate of biopsy-prover	
How should I take mycophenolate mofetil?		<u>Treatment and Management</u> MPA and the phenolic glucuronide metabolite of MPA (MPAG) are usually not removed by hemodialysis. However, at high MPAG plasma concentrations (>100 μg/mL), small amounts of MPAG are removed. By increasing excretion of the drug, MPA can be removed by bile acid					1 g	(±0.14) 0.85	(±5.73) 22.4	(±5.78) 29.8	rejection was similar across the age groups (3 months to <6 years, 6 years to <12 years, 12 years to 18 years). The overall biopsy- proven rejection rate at 6 months was comparable to adults. The combined incidence of graft loss (5%) and patient death (2%) at 12 months post-transplant was similar to that observed in adult kidney transplant patients.				
Take mycophenolate mofetil exactly as prescribed. Do not start along mycophenolate mofetil or change the doos upless your destart.	sequestrants, such as choles			asing excretion of the drug, w	PA can be removed by blie acid	(n=18)	5	(±0.58)	(±10.1)	(±10.7)	14.2 Heart Transplantation				
 Do not stop taking mycophenolate mofetil or change the dose unless your doctor tells you to. 					of mycophenolic acid (MPA),	<i>Pediatric Patients</i> The pharmacokinetic parameters of MP	A and MPAG have	ve been evaluated in	55 pediatric patients (rang	ing from 1 year to 18 years of	A double-blind, randomized, comparative, parallel-group, multicenter study in primary <i>de novo</i> heart transplant recipients was performed at centers in the United States (20), in Canada (1), in Europe (5) and in Australia (2). The total number of patients enrolled (ITT population) was 650; 72 never received study drug and 578 received study drug (Safety Population). Patients received mycophenolate mofetil 1.5 g				
If you miss a dose of mycophenolate mofetil, or you are not sure when you		an immunosuppressive agent; inosine monophosphate dehydrogenase (IMPDH) inhibitor.				age) receiving mycophenolate mofetil for oral suspension at a dose of 600 mg/m ² twice daily (up to a maximum of 1 g twice daily)) twice daily (n=289) or AZA 1.5 to 3 mg/kg/day (n=289), in combination with cyclosporine (Sandimmune® or Neoral®) and corticosteroids as maintenance immunosuppressive therapy. The two primary efficacy endpoints were: (1) the proportion of patients who, after				
took your last dose, take your prescribed dose of mycophenolate mofetil as soon as you remember. If your next dose is less than 2 hours away, skip the missed dose	5-isobenzofuranyl)-4-methyl- structural formula:	4-hexenoate. It has an	empirical formula of C ₂₃	₃ H ₃₁ NO ₇ , a molecular weight	of 433.50, and the following	Table 10. Mean (±SD) Computed Pharmacokinetic Parameters for MPA by Age and Time after Allogeneic Kidney Transplantation					transplantation, had at least one endomyocardial biopsy- proven rejection with hemodynamic compromise, or were re-transplanted or died, within the first 6 months, and (2) the proportion of patients who died or were re-transplanted during the first 12 months following				
and take your next dose at your normal scheduled time. Do not take 2 doses at the		,Ă,Ă,		~Ņ∕_		Age Group (n)	Time	T _{max} (h)	Dose Adjustedª C _{max} (mcg/mL)	Dose Adjustedª AUC ₀₋₁₂ (mcg•h/mL)	transplantation. Patients who prematurely disc and for the occurrence of death for 1 year. The analyses of the endpoints showed:	onunued treatment were followed for th	ne occurrence of allograft	rejection for up to 6 months	
 same time. Call your doctor if you are not sure what to do. Take mycophenolate mofetil capsules and tablets on an empty stomach, unless 	N/	iqi	осн₃			1 to less than 2 yr (6) ^d 1 to less than 6 yr (17)		3.03 (4.70)	10.3 (5.80)	22.5 (6.66)	 Rejection: No difference was established between mycophenolate mofetil and AZA with respect to biopsy-proven rejection with hemodynamic compromise. 				
your doctor tells you otherwise. Do not crush mycophenolate mofetil tablets.	d.D	CH _a					rlv (Dav 7)	1.63 (2.85) 0.940 (0.546)	13.2 (7.16)	27.4 (9.54) 33.2 (12.1)	 Survival: Mycophenolate mofetil was shown to be at least as effective as AZA in preventing death or re-transplantation at 1 year (see Table 13). 				
 Do not open or crush mycophenolate mofetil capsules If you are not able to swallow mycophenolate mofetil tablets or capsules, your 	in acidic medium (4.27 mg/r	Mycophenolate Mofetil is a white to off-white crystalline powder. It is slightly soluble in water (43 μgmL at pH 7.4); the solubility increased in acidic medium (4.27 mg/mL at pH 3.6). It is freely soluble in acetone, soluble in methanol and sparingly soluble in ethanol. The apparent partition coefficient in 1-octanol/water (pH 7.4) buffer solution is 238. The pKa values for MMF are 5.6 for the morpholino group and 8.5 for						1.16 (0.830)	11.7 (10.7)	26.3 (9.14) ^b	Table 13. De Novo Heart Transplantation Study Rejection at 6 Months/Death or Re-transplantation at 1 Year All Patients (ITT) Treated Patients				
doctor may prescribe mycophenolate mofetil oral suspension. This is a liquid	the phenolic group.	. ,				1 to less than 2 yr (4) ^d 1 to less than 6 yr (15)	0.	0.725 (0.276) 0.989 (0.511)	23.8 (13.4) 22.7 (10.1)	47.4 (14.7) 49.7 (18.2)		AZA Mycophenola N = 323 mofetil		Mycophenolate mofetil	
form of mycophenolate moretil. Your pharmacist will mix the medicine before you pick it up from a pharmacy.	containing 500 mg of MMF				ntaining 250 mg of MMF, tablets	6 to less than 12 yr (14) 12 to 18 yr (17)		1.21 (0.532) 0.978 (0.484)	27.8 (14.3) 17.9 (9.57)	61.9 (19.6) 53.6 (20.3)°	Discourse and all the file has a discourse	N = 327	'	N = 289	
 Do not mix mycophenolate mofetil oral suspension with any other medicine. 				roscarmellose sodium, magne ed # 3, gelatin, sodium lauryl	esium stearate, povidone [K-30], sulfate, and titanium dioxide.	1 to less than 2 yr (4) ^d		0.604 (0.208)	25.6 (4.25)	55.8 (11.6)	Biopsy-proven rejection with hemodynamic compromise at 6 months ^a	121 (38%) 120 (37%)		92 (32%)	
Mycophenolate mofetil oral suspension should not be mixed with any type of liquids before taking the dose.	Inactive ingredients in mycop [K-30], microcrystalline cellu		JSP 500 mg include crosc	armellose sodium, magnesiur	n stearate (Vegetable), povidone	1 to less than 6 yr (12) 6 to less than 12 yr (11)	e (Month 9) 🗕 –––––––––––––––––––––––––––––––––––	0.869 (0.479)	30.4 (9.16) 29.2 (12.6)	61.0 (10.7) 66.8 (21.2)	Death or re-transplantation at 1 year ^a Hemodynamic compromise occurred if an	49 (15.2%) 42 (12.8%)	, , ,	18 (6.2%)	
• Do not breathe in (inhale) or let mycophenolate mofetil powder or oral suspension	The opadry brown contains and titanium dioxide.	D&C blue #1 aluminum	lake, FD&C red #40 alum	ninum lake, Hypromellose, irc	on oxide red, polyethylene glycol	12 to 18 yr (14)		1.09 (0.518)	18.1 (7.29)	56.7 (14.0)	a 25% increase; cardiac index <2.0 L/min/m ² a 25% decrease; presence of new S ₂ gallop;	² or a 25% decrease; ejection fraction	≤30%; pulmonary artery	oxygen saturation ≤60% o	
come in contact with your skin or mucous membranes. o If you accidentally get the powder or oral suspension on the skin, wash the		12 CLINICAL PHARMACOLOGY 12.1 Mechanism of Action				a b adjusted to a dose of 600 mg/m² c n=20					the clinical condition. 14.3 Liver Transplantation	,	· ·		
area well with soap and water.	Mycophenolate mofetil (MMI				id (MPA), the active metabolite. PDH), and therefore inhibits the	d n=16 a subset of 1 to <6 yr					A double-blind, randomized, comparative, performed at centers in the United State	s (16), in Canada (2), in Europe	e (4) and in Australia	(1). The total number o	
 If you accidentally get the powder or oral suspension in your eyes or other mucous membranes, flush with plain water. 	de novo pathway of guanosi	ne nucleotide synthesis	without incorporation into I	DNA. Because T- and B-lymp	hocytes are critically dependent IPA has potent cytostatic effects	The mycophenolate mofetil for oral sus MPA AUC values in pediatric patients si					patients enrolled was 565. Per protocol, pa followed by mycophenolate mofetil 1.5 g tv kg/day orally, in combination with cyclo	wice daily orally or AZA 1 to 2 mg	j/kg/day intravenously foll	owed by AZA 1 to 2 mg	
If you take too much mycophenolate mofetil, call your doctor or the poison control	of guanosine or deoxyguan	sine reverses the cyto	static effects of MPA on	lymphocytes. MPA also sup	llospecific stimulation. Addition presses antibody formation by	at a dose of 1 g twice daily in the ea post-transplant MPA AUC values were ap	proximately 45% to	to 53% lower than the	ose observed in the later po		The actual median oral dose of AZA on st (range of 0.3 to 3.8 mg/kg/day) at 12	tudy was`1.5 mǵ/kg/day (range of (0.3 to 3.8 mg/kg/day) ir	itially and 1.26 mg/kg/da	
center right away.	endothelial cells and may in	nibit recruitment of leuk	cytes into sites of inflam	nmation and graft rejection. N	Ived in intercellular adhesion to IMF did not inhibit early events -1) and interleukin-2 (IL-2), but						experienced, in the first 6 months post death or re-transplantation, and (2) the p	-transplantation, one or more epis roportion of patients who experience	sodes of biopsy-proven ced graft loss (death o	and treated rejection o r re-transplantation) during	
 What should I avoid while taking mycophenolate mofetil? Avoid becoming pregnant. See "What is the most important information I should 	did block the coupling of thes		· · ·	production of interieukin-1 (iL	-1) and inteneukin-2 (iL-2), but	Data obtained from several studies were adjusted to 1 g oral dose). Mean $(\pm S (\pm 18.8) \text{ mcg} \cdot \text{h/mL}$ while mean $(\pm \text{SD}) \text{ N}$	D) MPA AUC (0-1	12h) for males (n=	79) was 32.0 (±14.5) an	l for females (n=41) was 36.5	.5 of allograft rejection and for the occurrence of graft loss (death or re-transplantation) for 1 year.				
know about mycophenolate mofetil?"	12.2 Pharmacodynamics There is a lack of information	regarding the pharmaco	dynamic effects of MMF.			are not of clinical significance.	max was 5.50	(±0.15) in the mate.	3 and 10.0 (±0.04) mog/m		In combination with corticosteroids and c 6 months and a similar rate of death or re-trans			rate of acute rejection a	
 Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. People who take mycophenolate mofetil have a higher risk of getting 	12.3 Pharmacokinetics Absorption					Geriatric Patients The pharmacokinetics of mycophenolate compared to younger transplant patients.	mofetil and its m	netabolites have not	been found to be altered ir	elderly transplant patients when	Table 14. De Novo Liver Transplantation Study	y Rejection at 6 Months/Death or Retra	-	ophenolate mofetil	
skin cancer (See "What is the most important information I should know about	absolute bioavailability of or	I MMF relative to intrav	enous MMF was 94%. Tw	vo 500 mg mycophenolate n	2 healthy volunteers, the mean nofetil tablets have been shown istituted mycophenolate mofetil	Drug Interaction Studies					Biopsy-proven, treated rejection at 6 months (i	N = 287		N = 278	
mycophenolate mofetil?") . Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor. This is especially important if your	oral suspension have been sl	own to be bioequivalent	to four 250 mg capsules.			Coadministration of MMF (1 g) and acy However, MPAG and acyclovir plasma AU				t change in MPA AUC and $\mathrm{C}_{\mathrm{max}}$	death or re- transplantation)	42 (14.6%)		107 (38.5%)	
skin is very fair or if you have a family history of skin cancer.	volunteers, and multiple dose	The mean (±SD) pharmacokinetic parameters estimates for MPA following the administration of MMF given as single doses to healthy volunteers, and multiple doses to kidney, heart, and liver transplant patients, are shown in Table 8 . The area under the plasma- concentration time curve (AUC) for MPA appears to increase in a dose-proportional fashion in kidney transplant patients receiving multiple oral doses of					<i>Hydroxides</i> g) was decreased	d when administered	to 10 rheumatoid arthritis	patients also taking Maalox® TC		ערידו) אד (17.070)	I		
 You should not donate blood while taking mycophenolate mofetil and for at least 6 weeks after stopping mycophenolate mofetil. 	MMF up to a daily dose of 3	(1.5g twice daily) (see	Table 8).		lthy Volunteers (Single Dose),	(10 mL gid). The C _{max} and AUC(0-24h) for MPA were 33% and 17% lower, respectively, than when MMF was administered alone under fasting conditions.					ler 1. "OSHA Hazardous Drugs." OSHA. http://www.osha.gov/SLTC/hazardousdrugs/index.html				
You should not donate sperm while taking mycophenolate mofetil and for 90 days	and Kidney, Heart, and Live				inity foruncers (onigie 2000),	Proton Pump Inhibitors (PPIs) Coadministration of PPIs (e.g., lansoprazole, pantoprazole) in single doses to healthy volunteers and multiple doses to transplant patients receiving mycophenolate mofetil has been reported to reduce the exposure to MPA. An approximate reduction of 30 to 70% in the C and									
after stopping mycophenolate mofetil.Mycophenolate mofetil may influence your ability to drive and use machines	Healthy Volunteers	Dose/Route	T _{max (h)}	C _{max} (mcg/mL)	Total AUC (mcg+h/mL)	receiving mycophenolate mofetil has been 25% to 35% in the AUC of MPA has been					Mycophenolate mofetil (MMF) has demonstra Populations (8.1)]. Mycophenolate mofetil tab				
(See "What are the possible side effects of mycophenolate mofetil?". If you	Single dose	1 g/oral	0.80 (±0.36) (n=129)	24.5 (±9.5) (n=129)	63.9 (±16.2) (n=117)	Cholestyramine Following single-dose administration of 1					crushed. Wearing disposable gloves is recom table after reconstitution. Avoid inhalation or	direct contact with skin or mucous m	embranes of the powder	contained in mycophenolat	
experience drowsiness, confusion, dizziness, tremor, or low blood pressure during treatment with mycophenolate mofetil, you should be cautious about driving or	Kidney Transplant Patients		(11=123)	C _{max}	Interdosing Interval AUC	MPA AUC decreased approximately 40% binding of recirculating MPAG with choles			rrupuon or enteronepauc re	circulation which may be due to	mofetil capsules. [see Dosage and Administrati 16.2 Mycophenolate Mofetil Capsules 250 m		idiing and disposal procedu	ires'.	
using heavy machines.	(twice daily dosing) Time After Transplantation	Dose/Route	T _{max (h)}	(mcg/mL)	(0- 12h) (mcg•h/mL)	Cyclosporine Cyclosporine (Sandimmune®) pharmaco twice daily of MMF in 10 stable kidne					Capsules White to off-white blend of mycophenolate m	ofetil filled in size "1" hard gelatin caps	ule with lvory Cap and lvo	ry Body, printed "SAL" on	
What are the possible side effects of mycophenolate mofetil? Mycophenolate mofetil can cause serious side effects, including:	5 days	1 g/iv	1.58 (±0.46) (n=31)	12.0 (±3.82) (n=31)	40.8 (±11.4) (n=31)	multiple doses of MMF were 3290 (± 8 700 (± 246) ng/mL, respectively, 1 week	822) ng•h/mL and before administrat	id 753 (±161) ng/m tion of MMF.	L, respectively, compared	to 3245 (±1088) ng•h/mL and	Sizes				
• See "What is the most important information I should know about mycophenolate	6 days	1.33 10.7 32.9				Cyclosporine A interferes with MPA enterohepatic recirculation. In kidney transplant patients, mean MPA exposure (AUC(0-12h)) was approximately 30-50% greater when MMF was administered without cyclosporine compared with when MMF was coadministered with					th Bottles of 120 NDC 64380-726-11				
 mofetil?" Low blood cell counts. People taking high doses of mycophenolate mofetil each 		1 g/oral	(n=31)	(n=31)	(n=31)	cyclosporine. This interaction is due to c tract, thereby preventing the excretion of taken into consideration when MMF is us	MPAG into the bile	e that would lead to e			Storage				
day may have a decrease in blood counts, including:	Early (Less than 40 days)	1 g/oral	1.31 (±0.76) (n=25)	8.16 (±4.50) (n=25)	27.3 (±10.9) (n=25)	Drugs Affecting Glucuronidation			oronon MDA		 Store at 20° to 25°C (68° to 77°F), [See USP controlled room temperature]. Dispense in light-resistant containers, such as the manufacturer's original containers. 				
 white blood cells, especially neutrophils. Neutrophils fight against bacterial infections. You have a higher chance of getting an infection when your white 	Early (Less than 40 days)	1.5 g/oral	1.21 (±0.81)	13.5 (±8.18)	38.4 (±15.4)	Concomitant administration of drugs inh 35% was observed with concomitant adm	ninistration of isavu	uconazole).		. , -	16.3 Mycophenolate Mofetil Tablets 500 mg				
blood cell count is low. This is most common from 1 month to 6 months after		1.0 y/01dl	(n=27)	(n=27)	(n=27)	Concomitant administration of telmisarta Telmisartan changes MPA's elimination b	y enhancing PPAR	R gamma (peroxisom			Tablets Pinkish brown colored, capsule shaped, film c	coated tablet with "SAL" engraved on on	e side and engraved "725"	on other side.	
	Late (Greater than 2	Late (default rillar) 1.5 g/oral (±0.24) (±12.1) (±35.4)					turn results in an enhanced UGT1A9 expression and glucuronidation activity.					Sizes			
 your transplant. red blood cells. Red blood cells carry oxygen to your body tissues. You have a 		1.5 g/01ai	(±0.24) (n=23)	(±12.1) (n=23)	(±35.4) (n=23)	<i>Ganciclovir</i> Following single-dose administration to	10 atable littless	transplant and state	o phormonal destination of the		Bottles of 100 NDC 64380-725 Bottles of 500 NDC 64380-725				

nigner chance of getting severe anernia when your red blood cell count is low. • **platelets.** Platelets help with blood clotting. After Transplantatio (mcg • h/mL) (mcg/mL) mL, respectively, after administration of intravenous ganciclovir alone. The mean (±SD) AUC and C, of MPA (n=12) after coadministration were 80.9 (±21.6) mcg•h/mL and 27.8 (±13.9) mcg/mL, respectively, compared to values of 80.3 (±16.4) μ g•h/mL and 30.9 Your doctor will do blood tests before you start taking mycophenolate mofetil and Early (Day before discharge) (±11.2) mcg/mL, respectively, after administration of MMF alone. 7 PATIENT COUNSELING INFORMATION 1.5 g/oral (±1.3) (± 6.8) (±20.8) (n=9) during treatment with mycophenolate mofetil to check your blood cell counts. Tell Oral Contraceptives Information for Patients See FDA-approved patient labeling (Medication Guide and Instructions for Use). A study of coadministration of mycophenolate mofetil (1 g twice daily) and combined oral contraceptives containing ethinylestradiol (0.02 mg to 0.04 mg) and levonorgestrel (0.05 mg to 0.20 mg), desogestrel (0.15 mg) or gestodene (0.05 mg to 0.10 mg) was conducted in 18 women with psoriasis over 3 consecutive menstrual cycles. Mean serum levels of LH, FSH and progesterone were not significantly affected. Mean AUC(0-24h) was similar for ethinylestradiol and 3-keto desogestrel; however, mean levonorgestrel AUC(0-24h) significantly descenced hu shout 15⁴. There was leave into retrinylestration and 3-keto desogestrel; however, mean levonorgestrel AUC(0-24h) significantly Inform females of repr your doctor right away if you have any signs of infection (See "What is the most Late (Greater than 6 1.5 g/oral (± 0.7) (n=52) (±9.4) (±20.4) (n=49) important information I should know about mycophenolate mofetil?"), including any Pregnancy loss and malformation Inform females of reproductive potential and pregnant women that use of mycophenolate mofetil during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformations. Advise that they must use an acceptable form of contraception [see Warnings and Precautions (5.1), Use in Specific Populations (8.1, 8.3)]. unexpected bruising or bleeding. Also, tell your doctor if you have unusual tiredness, Liver transplant Patients Interdosing Interval AUC (0- 12h) decreased by about 15%. There was large inter-patient variability (%CV in the range of 60% to 70%) in the data, especially for ethinylestradiol. Cmax (twice daily dosing) Time After Transplantation T_{max (h)} Dose/Route lack of energy, dizziness or fainting. (mcg•h/mL) Sevelamer Encourage pregnant women to enclose in the Pregnancy Exposure Registry. This registry monitors pregnancy outcomes in women exposed to mycophenolate [see Use in Specific Populations (8.1)]. Concomitant administration of sevelamer and MMF in adult and pediatric patients decreased the mean MPA C_{max} and AUC (0-12h) by 36% and • **Stomach problems.** Stomach problems including intestinal bleeding, a tear in 34.0 (±17.4) (n=22) 26% respectively. 4 to 9 days 1 g/iv (±0.517) (n=22) (± 12.7) (n=22)your intestinal wall (perforation) or stomach ulcers can happen in people who Discuss pregnancy testing, pregnancy prevention and planning with females of reproductive potential [see Use in Specific Populations (8.3)]. Antimicrobials Antimicrobials eliminating beta-glucuronidase-producing bacteria in the intestine (e.g. aminoglycoside, cephalosporin, fluoroguinolone, and take mycophenolate mofetil. Bleeding can be severe and you may have to be Early (5 to 8 days) penicillin classes of antimicrobials) may interfere with the MPAG/MPA enterohepatic recirculation thus leading to reduced systemic MPA 1.5 g/oral (±0.432) (n=20) (±11.9) (n=20) (±6.76) (n=20) Females of reproductive potential must use an acceptable form of birth control during the entire mycophenolate mofetil therapy and hospitalized for treatment. Call your doctor right away if you have sudden or Dosure. Information concerning antibiotics is as follows: Trimethoprim/Sulfamethoxazole: Following single-dose administration of MMF (1.5 g) to 12 healthy male volunteers on day 8 of a for 6 weeks after stopping mycophenolate motetil, unless the patient chooses abstinence Mycophenolate motetil may reduce effectiveness of oral contraceptives. Use of additional barrier contraceptive methods is recommended [see Use in Specific severe stomach-area pain or stomach- area pain that does not go away, or if you 49.3 (±14.8) (n=6) 10-day course of trimethoprim 160 mg/sulfamethoxazole 800 mg administered twice daily, no effect on the bioavailability of MPA was observed. The mean (\pm SD) AUC and C_{max} of MPA after concomitant administration were 75.2 (\pm 19.8) mcg•h/mL and 34.0 (\pm 6.6) mcg/mL, respectively, compared to 79.2 (\pm 27.9) mcg•h/mL and 34.2 (\pm 10.7) mcg/mL, respectively, after administration of Late (Greater than 6 (± 0.51) 1.5 g/oral (± 11.7) Populations (8.3)]. months) have diarrhea. For patients who are considering pregnancy, discuss appropriate alternative immunosuppressants with less potential for embryofetal toxicity. Risks and benefits of mycophenolate mofetil should be discussed with the patient. Advise sexually active male patients and/or their partners to use effective contraception during the treatment of the male patient The most common side effects of mycophenolate mofetil include: MMF alone ^aAUC(0-12h) values quoted are extrapolated from data from samples collected over 4 hours. Norfloxacin and Metronidazole: Following single-dose administration of MMF (1 g) to 11 healthy volunteers on day 4 of a 5-day and for at least 90 days after cessation of treatment. This recommendation is based on findings of animal studies [see Use in Specific Populations (8.3), Nonclinical Toxicology (13.1)]. diarrhea changes in laboratory blood levels, course of a combination of norfloxacin and metronidazole, the mean MPA AUC (0-48h) was significantly reduced by 33% compared to the administration of MMF alone (p<0.05). The mean (\pm SD) MPA AUC (0-48h) after coadministration of MMF with norfloxacin or In the early post-transplant period (less than 40 days post-transplant), kidney, heart, and liver transplant patients had mean MPA blood problems including low including high levels of blood sugar AUCs approximately 20% to 41% lower and mean C_{max} approximately 32% to 44% lower compared to the late transplant period (i.e., 3 to metronidazole separately was 48.3 (±24) mcg-h/mL and 42.7 (±23) mcg-h/mL, respectively, compared with 56.2 (±24) mcg-h/mL **17.2 Development of Lymphoma and Other Malignancies** 6 months post-transplant) (non-stationarity in MPA pharmacokinetics) white and red blood cell counts (hyperglycemia) Inform patients that they are at increased risk of developing lymphomas and other malignancies, particularly of the skin, due to immunosuppression [see Warnings and Precautions (5.2)]. after administration of MMF alone. Mean MPA AUC values following administration of 1 g twice daily intravenous mycophenolate mofetil over 2 hours to kidney transplant Ciprofloxacin and Amoxicillin Plus Clavulanic Acid: A total of 64 mycophenolate mofetil -treated kidney transplant recipients received either stomach problems including diarrhea, infections patients for 5 days were about 24% higher than those observed after oral administration of a similar dose in the immediate post-transplant oral ciprofloxacin 500 mo twice daily or amoxicillin plus clavulanic acid 375 mo three times daily for 7 or at least 14 days, respectively. Advise patients to limit exposure to sunlight and ultraviolet (UV) light by wearing protective clothing and use of sunscreen blood pressure problems Approximately 50% reductions in median trough MPA concentrations (pre-dose) from baseline (mycophenolate mofetil alone) were observed in 3 days following commencement of oral ciprofloxacin or amoxicillin plus clavulanic acid. These reductions in trough MPA for a f constipation, nausea and vomiting In liver transplant patients, administration of 1 g twice daily intravenous mycophenolate mofetil followed by 1.5 g twice daily oral fast heart beat rash mycophenolate moretil resulted in mean MPA AUC estimates similar to those found in kidney transplant patients administered 1 g concentrations tended to diminish within 14 days of antimicrobial therapy and ceased within 3 days of discontinuation of antibiotics. Inform patients that they are at increased risk of developing a variety of infections due to immunosuppression. Instruct them to contact Rifampin: In a single heart-lung transplant patient, fatter correction for dose, a 67% decrease in MPA exposure (AUC(0-12h)) has been observed with concomitant administration of MMF and rifampin. swelling of the lower legs, ankles
 nervous system problems such as mycophenolate mofetil twice daily. headache, dizziness and tremor and feet Effect of Food 17.4 Blood Dyscrasias Inform patients that they are at increased risk for developing blood adverse effects such as anemia or low white blood cells Advise patients to immediately contact their healthcare provider if they experience any evidence of infection, unexpected bruising, or bleeding, or any other manifestation of bone marrow suppression [see Warnings and Precautions (5.4)]. Food (27 g fat, 650 calories) had no effect on the extent of absorption (MPA AUC) of MMF when administered at doses of 1.5 g twice daily 13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility Side effects that can happen more often in children than in adults takin to kidney transplant patients. However, MPA C_{max} was decreased by 40% in the presence of food [see Dosage and Administration (2.1)]. In a 104-week oral carcinogenicity study in mice, MMF in daily doses up to 180 mg/kg was not tumorigenic. The highest dose tested was mycophenolate mofetil include: Distribution 0.4 times the recommended clinical dose (2 g/day) in renal transplant patients and 0.3 times the recommended clinical dose (2 g/day) in cardiac transplant patients when corrected for differences in body surface area (BSA). In a 104-week oral carcinogenicity study in rats, MMF in daily 17.5 Gastrointestinal Tract Complications The mean (±SD) apparent volume of distribution of MPA in 12 healthy volunteers was approximately 3.6 (±1.5) L/kg. At clinically relevant stomach area pain vomiting Inform patients that mycophenolate mofetil can cause gastrointestinal tract complications including bleeding, intestinal perforations, and concentrations, MPA is 97% bound to plasma albumin. The phenolic glucuronide metabolite of MPA (MPAG) is 82% bound to plasma albumin at MPAG concentration ranges that are normally seen in stable kidney transplant patients; however, at higher MPAG concentrations doses up to 15 mg/kg was not tumorigenic. The highest dose was 0.07 times the recommended clinical dose in kidney transplant patients gastric or duodenal ulcers. Advise the patient to contact their healthcare provider if they have symptoms of gastrointestinal bleeding, or sudden onset or persistent abdominal pain [see Warnings and Precautions (5.5)]. sore throat fever and 0.05 times the recommended clinical dose in heart transplant patients when corrected for BSA. While these animal doses were lower than those given to patients, they were maximal in those species and were considered adequate to evaluate the potential for human risk (observed in patients with kidney impairment or delayed kidney graft function), the binding of MPA may be reduced as a result of competition infection colds (respiratory tract infections) tween MPAG and MPA for protein binding. Mean blood to plasma ratio of radioactivity concentrations was approximately 0.6 indicating [see Warnings and Precautions (5.2)]. 17.6 Immunizations Inform patients that mycophenolate mofetil can interfere with the usual response to immunizations. Before seeking vaccines on their own, advise patients to discuss first with their physician. *[see Warnings and Precautions (5.7)]*. high blood pressure that MPA and MPAG do not extensively distribute into the cellular fractions of blood. pain The genotoxic potential of MMF was determined in five assays. MMF was genotoxic in the mouse lymphoma/thymidine kinase assay and the *in vivo* mouse micronucleus assay. MMF was not genotoxic in the bacterial mutation assay, the yeast mitotic gene conversion assay or In vitro studies to evaluate the effect of other agents on the binding of MPA to human serum albumin (HSA) or plasma proteins showed blood infection (sepsis) low white blood cell count that salicylate (at 25 mg/dL with human serum albumin) and MPAG (at ≥ 460 mcg/mL with plasma proteins) increased the free fraction of the Chinese hamster ovary cell chromosomal aberration assay. 17.7 Administration Instructions Advise patients not to crush mycophenolate mofetil tablets and not to open mycophenolate mofetil capsules. Advise patients to avoid inhalation or contact of the skin or mucous membranes with mycophenolate mofetil capsules. If such low red blood cell count MPA. MPA at concentrations as high as 100 mcg/mL had little effect on the binding of warfarin, digoxin or propranolol, but decreased the diarrhea MMF had no effect on fertility of male rats at oral doses up to 20 mg/kg/day. This dose represents 0.1 times the recommended clinical dose binding of theophylline from 53% to 45% and phenytoin from 90% to 87%. in renal transplant patients and 0.06 times the recommended clinical dose in cardiac transplant patients when corrected for BSA. In a female These are not all of the possible side effects of mycophenolate mofetil. Tell your db contact occurs, they must wash the area of contact thoroughly with soap and water. In case of ocular contact, rinse eyes with plain fertility and reproduction study conducted in rats, oral doses of 4.5 mg/kg/adv caused malformations (principally of the head and eyes) in the first generation offspring in the absence of maternal toxicity. This dose was 0.02 times the recommended clinical dose in renal Eliminatio doctor about any side effect that bothers you or that does not go away. Mean (±SD) apparent half-life and plasma clearance of MPA are 17.9 (±6.5) hours and 193 (±48) mL/min following oral administration. Advise patients to take a missed dose as soon as they remember, except if it is closer than 2 hours to the next scheduled dose; in this transplant patients and 0.01 times the recommended clinical dose in cardiac transplant patients when corrected for BSA. No effects on fertility case they should continue to take mycophenolate mofetil at the usual times. Call your doctor for medical advice about side effects. You may report side effects or reproductive parameters were evident in the dams or in the subsequent generation. The parent drug, MMF, can be measured systemically during the intravenous infusion; however, approximately 5 minutes after the infusion 17.8 Blood Donation 14 CLINICAL STUDIES is stopped or after oral administration, MMF concentrations are below the limit of quantitation (0.4 mcg/mL). to FDA at 1-800-FDA-1088. Advise patients not to donate blood during therapy and for at least 6 weeks following discontinuation of mycophenolate mofetil. Metabolism to MPA occurs pre-systemically after oral dosing. MPA is metabolized principally by glucuronyl transferase to form MPAG. 14.1 Kidney Transplantation You may also report side effects to Strides Pharma Inc. at 1-877-244-9825 or go to 17.9 Semen Donation which is not pharmacologically active. In vivo, MPAG is converted to MPA during enterohepatic recirculation. The following metabolites Adults The three *de novo* kidney transplantation studies compared two dose levels of oral mycophenolate mofetil (1 g twice daily and 1.5 g twice (7A) dvise males of childbearing potential not to donate semen during therapy and for 90 days following discontinuation of mycophenolate www.strides.com of the 2-hydroxyethyl-morpholino moiety are also recovered in the urine following oral administration of MMF to healthy subjects: carboxymethyl)-morpholine, N-(2-hydroxyethyl)-morpholine, and the N-oxide of N-(2-hydroxyethyl)-morpholine. daily) with azathioprine (2 studies) or placebo (1 study) to prevent acute rejection episodes. One of the two studies with azathioprine (AZA) 17.10 Potential to Impair Driving and Use of Machinery Advise patients that mycophenolate mofetil can affect the ability to drive or operate machines. Patients should avoid driving or operating How should I store mycophenolate mofetil capsules and tablets? control arm also included anti-thymocyte globulin (ATGAM®) induction therapy. The geographic location of the investigational sites of these Due to the enterohepatic recirculation of MPAG/MPA, secondary peaks in the plasma MPA concentration-time profile are usually observed studies are included in Table 11. • Store mycophenolate mofetil capsules and tablets at room temperature 6 to 12 hours post-dose. Bile sequestrants, such as cholestyramine, reduce MPA AUC by interfering with this enterohepatic recirculation of the drug [see Overdose (10) and Drug Interaction Studies below]. nachines if they experience somnolence, confusion, dizziness, tremor or hypotension during treatment with mycophenolate mofetil. In all three *de novo* kidney transplantation studies, the primary efficacy endpoint was the proportion of patients in each treatment group who experienced treatment failure within the first 6 months after transplantation. Treatment failure was defined as biopsy-proven acute between 20° to 25°C (68° to 77°F). Dispense in light-resistant containers, such as Manufactured by: Excretion rejection on treatment or the occurrence of death, graft loss or early termination from the study for any reason without prior biopsy-proven Strides Pharma Science Ltd the manufacturer's original containers. Negligible amount of drug is excreted as MPA (less than 1% of dose) in the urine. Orally administered radiolabeled MMF resulted in complete engaluru - 562106. Indi rejection • Keep mycophenolate mofetil tablets in light resistant container that it comes in. recovery of the administered dose, with 93% of the administered dose recovered in the urine and 6% recovered in feces. Most (about 87%) Mycophenolate mofetil, in combination with corticosteroids and cyclosporine, reduced (statistically significant at 0.05 level) of the administered dose is excreted in the urine as MPAG. At clinically encountered concentrations, MPA and MPAG are usually not removed Distributed by Keep mycophenolate mofetil and all medicines out of the reach of children. the incidence of treatment failure within the first 6 months following transplantation (Table 11). Patients who prematurely by hemodialysis. However, at high MPAG plasma concentrations (> 100 mcg/mL), small amounts of MPAG are removed. Strides Pharma Ir discontinued treatment were followed for the occurrence of death or graft loss, and the curulative incidence of graft loss and patient death combined are summarized in **Table 12**. Patients who prematurely discontinued treatment were not followed East Brunswick, NJ 08816 Increased plasma concentrations of MMF metabolites (MPA 50% increase and MPAG about a 3-fold to 6-fold increase) are observed in General Information about the safe and effective use of mycophenolate mofetil. patients with renal insufficiency [see Specific Populations]. for the occurrence of acute rejection after termination. Medicines are sometimes prescribed for purposes other than those listed in a Revised: 01/2020 Specific Populations Table 11. Treatment Failure in De Novo Kidney Transplantation Studies Medication Guide. Do not use mycophenolate mofetil for a condition for which it was Patients with Renal Impairment The mean $(\pm SD)$ pharmacokinetic parameters for MPA following the administration of oral MMF given as single doses to non-transplant
 Mycophenolate mofetil
 2 g/
 Mycophenolate mofetil
 AZA

 day (n=167 patients)
 3 g/day (n=166 patients)
 1 to 2 mg/kg/day (n=166 patients)
 not prescribed. Do not give mycophenolate mofetil to other people, even if they have USA Study (N=499 patients) subjects with renal impairment are presented in $\ensuremath{\textbf{Table 9}}.$ the same symptoms that you have. It may harm them. In a single-dose study, MMF was administered as a capsule or as an intravenous infusion over 40 minutes. Plasma MPA AUC observed All 3 groups received anti-thymocyte globulin induction sporine and cortion after oral dosing to volunteers with severe chronic renal impairment (GFR < 25 mL/min/1.73 m²) was about 75% higher relative to that observed in healthy volunteers (GFR > 80 mL/min/1.73 m²). In addition, the single-dose plasma MPAG AUC was 3-fold to 6-fold higher in This Medication Guide summarizes the most important information about 31.1% 31.3% 47.6% All treatment failures mycophenolate mofetil. If you would like more information, talk with your doctor. volunteers with severe renal impairment than in volunteers with mild renal impairment or healthy volunteers, consistent with the known renal Early termination without price 9.6% 6.0% elimination of MPAG. No data are available on the safety of long-term exposure to this level of MPAG. 12.7% You can ask your doctor or pharmacist for information about mycophenolate mofetil Patients with Delayed Graft Function or Nonfunction iopsy-proven rejection episod that is written for health professionals. 19.8% 17.5% 38.0% n patients with delayed renal graft function post-transplant, mean MPA AUC(0-12h) was comparable to that seen in on treatment post-transplant patients without delayed renal graft function. There is a potential for a transient increase in the free fraction What are the ingredients in mycophenolate mofetil capsules and tablets? cophenolate mofetil 2 day (n=173 patients) Mycophenolate mofetil 3 g/day (n=164 patients) and concentration of plasma MPA in patients with delayed renal graft function. However, dose adjustment does not appear to be necessary in patients with delayed renal graft function. Mean plasma MPAG AUC(0-12h) was 2-fold to 3-fold higher Europe/Canada/ Australia Study (N=503 patients) 100 to 150 mg/day (n=166 patients) Active Ingredient: mycophenolate mofetil than in post-transplant patients without delayed renal graft function [see Dosage and Administration (2.5)]. No induction treatment tered: all 3 groups rece e and corticosteroids Inactive Ingredients: In eight patients with primary graft non-function following kidney transplantation, plasma concentrations of MPAG 38.2% 34.8% 50.0% Mycophenolate mofetil 250 mg capsules: croscarmellose sodium, magnesium accumulated about 6-fold to 8-fold after multiple dosing for 28 days. Accumulation of MPA was about 1-fold to 2-fold. Early termination without price 13.9% 15.2% 10.2% stearate, povidone [K-30], microcrystalline cellulose. The capsule shells contain yellow The pharmacokinetics of MMF are not altered by hemodialysis. Hemodialysis usually does not remove MPA or MPAG. acute rejection At high concentrations of MPAG (> 100 mcg/mL), hemodialysis removes only small amounts of MPAG. iron oxide, FD&C red # 3, gelatin, sodium lauryl sulfate, and titanium dioxide. iopsy-proven rejection episod 19.7% 15.9% 35.5% Patients with Hepatic Impairment treatment The mean $(\pm SD)$ pharmacokinetic parameters for MPA following the administration of oral MMF given as single doses to Mycophenolate mofetil 500 mg tablets: croscarmellose sodium, magnesium stearate Europe Study (N=491 patient nenolate mofetil 2 g/ Myc Placebo (n=166 patients) phenolate mofetil 3 non-transplant subjects with hepatic impairment is presented in Table 9. day (n=165 patients) day (n=160 patients) (Vegetable), povidone [K-30], microcrystalline cellulose, opadry brown. In a single-dose (1 g oral) study of 18 volunteers with alcoholic cirrhosis and 6 healthy volunteers, hepatic MPA glucuronidation process No induction treatment adr istered; all 3 groups receiv ne and corticosteroids The opadry brown contains FD&C blue #1 aluminum lake, FD&C red #40 aluminum appeared to be relatively unaffected by hepatic parenchymal disease when pharmacokinetic parameters of healthy volunteers and alcoholic 30.3% 38.8% 56.0% cirrhosis patients within this study were compared. However, it should be noted that for unexplained reasons, the healthy volunteers in this study had about a 50% lower AUC as compared to healthy volunteers in other studies, thus making comparisons between volunteers with lake, Hypromellose, iron oxide red, polyethylene glycol and titanium dioxide. Early termination without price 11.5% 22.5% 7.2% alcoholic cirrhosis and healthy volunteers difficult. ite rejection Manufactured by: Biopsy-proven rejection episode Table 9. Pharmacokinetic Parameters for MPA [mean (±SD)] Following Single Doses of MMF Capsules in Chronic Renal and Hepatic 17.0% 13.8% 46.4% Strides Pharma Science Ltd. on treatment Impairment Bengaluru - 562106, India *Does not include death and graft loss as reason for early termination Pharmacokinetic Parameters for Renal Impairment No advantage of mycophenolate mofetil at 12 months with respect to graft loss or patient death (combined) was established (Table 12). AUC(0-96h) Distributed by: Numerically, patients receiving mycophenolate mofetil 2 g/day and 3 g/day experienced a better outcome than controls in all three studies; Dose T_{max (h)} C_{max} (mcg/mL) (mcg•h/mL) patients receiving mycophenolate motetil 2 g/day experienced a better outcome than mycophenolate motetil 3 g/day in two of the three studies Strides Pharma Inc. Patients in all treatment groups who terminated treatment early were found to have a poor outcome with respect to graft loss or patient death Healthy Voluntee 1 g 0.75 25.3 GFR greater than 80 mL/min/1.73 m² 45.0 (±22.6) East Brunswick, NJ 08816 at 1 vea (±0.27) (±7.99) Table 12. De Novo Kidney Transplantation Studies Cumulative Incidence of Combined Graft Loss or Patient Death at 12 Months Revised: 01/2020 Mycophenolate mofetil 3 g/day Study Mycophenolate mofetil 2 Control (AZA or Placebo) 0.75 (±0.27) GFR 50 to 80 mL/min/1.73 m² (n=6) 26.0 (±3.82) 59.9 (±12.9) 1 g g/day This Medication Guide has been approved by the U.S. Food and Drug Administration. Moderate Renal Impairment GFR 25 to 49 mL/min/1.73 m² (n=6) 8.5% 11.5% 12.2% 1 g 0.75 (±0.27) 19.0 (±13.2) 52.9 (±25.5) 11.0% 13.6% urope/Canad Severe Renal Impairment GFR less than 25 mL/min/1.73 m² (n=7) 10.0% 11.5% 1 g 1.00 (±0.41) 16.3 (±10.8) 78.6 (±46.4) Europe 8.5%

500 x 600 mm

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ARTWORK DETAIL LABEL

Product	MYCOPHENOLATE MOFETIL CAPSULES, USP 250	mg & MYCOPHENC	OLATE MOFETIL TABL	ETS, USP 500mg			
Buyer/Country	STRIDES PHARMA INC -US	RMA INC -US Component Outsert with medication gu					
Dimension	500 x 600 mm			Pack			
New Item Code	1040185	Old Item Code	1039986				
Colour Shades	Black			No. of Colours	1		
Change Control No.	Record Number: 244690			Artwork Version	7.0		
Design/Style	Front and Back printing, to be supplied in the folded	booklet form with	pasting and folded siz	e: 37 x 36 mm.			
Substrate	40/45 GSM Paper.						
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.						
Autocartonator Requirements	NA						
provided to you. In cas	r: Before processing, please ensure that the ARTWO se of any FONTS/DESIGN are Mis-matching with the p TO THE ARTWORK WITHOUT WRITTEN INSTRUCT	APPROVED ARTW	ORK, please inform P				

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