Space for 15 Digit - Sequential 2D Data matrix Barcode shall be printed by the vendor.

**Position / Orientation shall be changed depending upon the Printer's Machine suitability.**

POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution 1037489

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**MEDICATION GUIDE**

# POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution

(pol″ ee eth′ i leen glye′ kol 3350, soe′ dee um klor′ ide, soe′ dee um bye kar′ bo nate and poe tas′ ee um klor′ ide)

Read this Medication Guide before you start taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**What is the most important information I should know about polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

**Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and other osmotic bowel preparations can cause serious side effects, including:**

**Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.**

**These changes can cause:**

- **abnormal heartbeats that can cause death**
- **seizures**. This can happen even if you have never had a seizure.
- **kidney problems**

**Your chance of having fluid loss and changes in body salts with polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is higher if you:**

- have heart problems
- have kidney problems
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS)

**Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution:**

- vomiting that prevents you from keeping down the solution
- dizziness
- urinating less often than normal
- headache

**See Section "What are the possible side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution" for more information about side effects.**

**What is polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is a prescription medicine used by adults to clean the colon before a colonoscopy. Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is safe and effective for use in pediatric patients aged 6 months and older.

**Who should not take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

Do not take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)
- an allergy to any of the ingredients in polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. See the end of this leaflet for a complete list of ingredients in polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

**What should I tell my healthcare provider before taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

**Before you take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, tell your healthcare provider if you:**

- have heart problems
- have stomach or bowel problems
- have ulcerative colitis
- have problems with swallowing or gastric reflux
- have a history of seizures
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- any other medical conditions
- are pregnant. It is not known if polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution passes into your breast milk. You and your healthcare provider should decide if you will take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution while breastfeeding.

**Tell your healthcare provider about all the medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements.

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

**Especially tell your healthcare provider if you take:**

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- laxatives

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

**You must read, understand, and follow these instructions to take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution the right way.**

- Take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution exactly as your healthcare provider tells you to take it.
- Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until the discomfort goes away.
- Continue drinking until the watery stool is clear and free of solid matter. This usually requires 3 liters and it is best to drink all of the solution.
- **Do not take undissolved polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution's powder that has not been mixed with water (diluted), it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each jug of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution must be reconstituted with water (diluted) to 4 liters total volume before drinking.
- Do not take other laxatives while taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.
- **Do not eat solid foods on the day before your colonoscopy and until after your colonoscopy**. Drink only clear liquids:
  - the day before your colonoscopy
  - while taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution
  - after taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution until 2 hours before your colonoscopy

**What are the possible side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution can cause serious side effects, including:

- **See Section "What is the most important information I should know about polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?"**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
  - vomiting
  - nausea
  - bloating
  - dizziness
  - stomach (abdominal) cramping
  - headache
  - urinate less than usual
  - trouble drinking clear liquid
- **heart problems. Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may cause irregular heartbeats.**
- **seizures**
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution include:

- nausea
- stomach (abdominal) fullness
- bloating
- stomach (abdominal) cramps
- vomiting
- anal irritation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

- Store polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution at room temperature, between 59°F to 86°F (15°C to 30°C).

**Keep polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and all medicines out of the reach of children.**

**General information about the safe and effective use of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for a condition for which it was not prescribed. Do not give polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes important information about polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

For more information go to www.stridesshasun.com or call Strides Pharma Inc. at 1-877-244-9825.

**What are the ingredients in polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?**

**Active ingredients**: Polyethylene glycol 3350 USPNF, sodium bicarbonate USP, sodium chloride USP and potassium chloride USP.

**Inactive ingredients**: Flavor lemon or flavor orange (in its respective flavor pack) with acesulfame potassium

Manufactured by:
**Strides Shasun Limited**
Bengaluru - 560076, India.

Distributed by:
**Strides Pharma Inc.**
East Brunswick, NJ 08816

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 10/2018

Revision: 3

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200 x 370 mm FRONT SIDE

200 x 370 mm BACK SIDE

7820

7821

## ARTWORK DETAIL LABEL

| | | | | | |
|---|---|---|---|---|---|
| **Product** | **POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution** | | | | |
| Buyer/Country | STRIDES PHARMA INC | Component | Outsert ( Medication Guide ) | | |
| **Dimension** | **200 x 370 mm** | | | Pack | - |
| **New Item Code** | **1037489** | Old Item Code | 1030995 | | |
| Colour Shades | Black | | | No. of Colours | 1 |

| | | | |
|---|---|---|---|
| Change Control No. | PC-ODF/2017/784 Record Number: 138057 | Artwork Version | 4.0 |
| Design/Style | Front & Back Printing. Booklet Form. (Folded size: 35 x 35mm). To be supplied in the folded Booklet form with pasting. | | |
| Substrate | 40/45 GSM Paper. | | |
| Special Instructions | PRINTING CLARITY TO BE CLEAR AND SHARP. | | |
| Autocartonator Requirements | NA | | |

**Caution to the printer:** Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

RD/PD/003/F-08/R0

| PRODUCT INFORMATION | |
|---|---|
| PRODUCT/BRAND NAME | PEG-3350 for Oral Solution - Without Flavor |
| COMPONENT | Pack insert |
| FG CODE | 3007133 |
| MARKET TYPE | Export |
| MARKET(S) | USA |
| MFG LOCATION | KRSG |
| NEW MATERIAL CODE | 1037489 |
| OLD MATERIAL CODE | 1030995 |
| REQUEST TYPE | Change |
| WORKFLOW | Change Control Export Flow |
| STRENGTH | -- |
| PACK SIZE | --- |
| CUSTOMER APPROVAL | Yes |

**FINALIZATION SUMMARY**

| ACTION | DEPARTMENT | ACTION BY | ACTION ON |
|---|---|---|---|
| Initiate,User Authorization ,CustomerCopy/Artw ork Documents Upload | Packaging Development-AW | R Peddarami Reddy | 10/26/2018 10:57 AM |
| Checklist Approval/Reject | Packaging Development-AW | R Peddarami Reddy | 10/26/2018 10:59 AM |
| Checklist Approva/Reject | Packaging Development-Tech | Suresh Sorapalli | 10/26/2018 11:09 AM |
| Checklist Approva/Reject | FDD/TTD | B Satish Kumar | 10/26/2018 02:43 PM |
| Checklist Approva/Reject | Production | Soumendra M | 10/26/2018 04:37 PM |
| Checklist Approva/Reject | Regulatory Affairs | Selvakumar Subramanian | 10/29/2018 10:25 AM |
| Checklist Approva/Reject | Quality Assurance | Chandrasekar | 10/29/2018 10:33 AM |
| Checklist Approva/Reject | Marketing/BD | Mahesh Gupta | 10/29/2018 10:34 AM |

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