

POLYETHYLENE GLYCOL- polyethylene glycol powder, for solution
Harmon Stores, Inc

Polyethylene Glycol 3350 powder for solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 g (cap filled to line)

Purpose

Osmotic Laxative

Use

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

WARNINGS

Allergy alert

Do not use if you are allergic to polyethylene glycol

Do not use if you have kidney disease, except under the advice and supervision of a doctor

Ask a doctor before use if you have

- nausea, vomiting or abdominal pain
- a sudden change in bowel habits that lasts over 2 weeks
- irritable bowel syndrome

Ask a doctor of pharmacist before use if you are taking a prescription drug

- **When using this product** you may have loose, watery, more frequent stools

Stop use and ask a doctor if

- you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.
- you get diarrhea
- you need to use a laxative for longer than 1 week

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed unless advised by your doctor**
- the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap)
- adults and children 17 years of age and older:

- fill to top of white section in cap which is marked to indicate the correct dose (17 g)
- stir and dissolve in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
- use once a day
- use no more than 7 days
- children 16 years of age or under: ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)
- tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Inactive Ingredient

none

Questions or comments?

1-877-753-3935

Made in India

*Miralax[®] is a registered trademark of Bayer Consumer Care Holdings LLC

Distributed by Liberty

Procurement, Inc. 650 Liberty

Ave. Union, NJ 07083 USA

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Revised: 01/2017

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 63940-762-03

Polyethylene Glycol 3350

Powder for Solution

OSMOTIC LAXATIVE

Polyethylene Glycol 3350 powder for solution increases frequency of bowel movements and softens the stool.

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**
- **Dissolves in any beverage**
- **Sugar Free**

TAMPER-EVIDENT: DO NOT USE IF PRINTED FOIL SEAL UNDER CAP IS MISSING, OPEN OR BROKEN

7 Once-Daily Doses

NET WT 4.15 OZ (119 g)



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 63940-762-04

Polyethylene Glycol 3350

Powder for Solution

OSMOTIC LAXATIVE

Polyethylene Glycol 3350 powder for solution increases frequency of bowel movements and softens the stool.

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**
- **Dissolves in any beverage**
- **Sugar Free**

TAMPER-EVIDENT: DO NOT USE IF PRINTED FOIL SEAL UNDER CAP IS MISSING, OPEN OR BROKEN

14 Once-Daily Doses

NET WT 8.3 OZ (238 g)



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 63940-762-05

Polyethylene Glycol 3350

Powder for Solution

OSMOTIC LAXATIVE

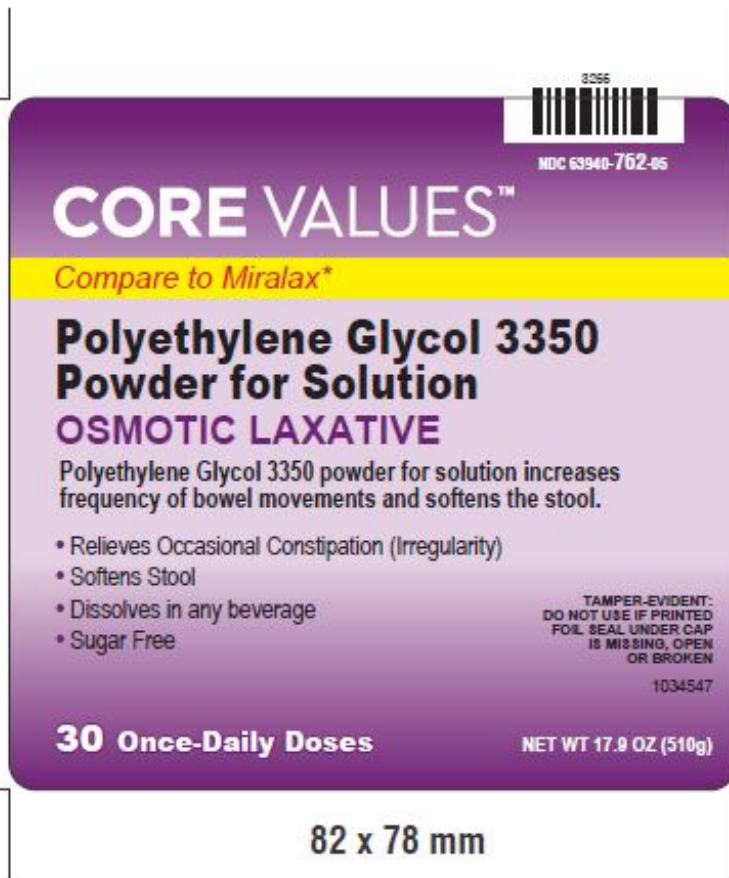
Polyethylene Glycol 3350 powder for solution increases frequency of bowel movements and softens the stool.

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**
- **Dissolves in any beverage**
- **Sugar Free**

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30 Once-Daily Doses

NET WT 17.9 OZ (510 g)



82 x 78 mm

POLYETHYLENE GLYCOL

polyethylene glycol powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-762
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	17 g in 17 g

Product Characteristics

Color	WHITE ((colorless upon dissolution))	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:63940-762-03	119 g in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2016	
2	NDC:63940-762-04	238 g in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2016	
3	NDC:63940-762-05	510 g in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	08/24/2016	

Labeler - Harmon Stores, Inc (804085293)

Registrant - Strides Shasun Limited (918513263)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Shasun Limited		918513263	ANALYSIS(63940-762) , MANUFACTURE(63940-762) , PACK(63940-762)

Revised: 5/2017

Harmon Stores, Inc