

POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
Gericare Pharmaceuticals

Polyethylene Glycol 3350, Powder for Solution

SPL UNCLASSIFIED

Drug Facts

OTC - ACTIVE INGREDIENT SECTION

Polyethylene Glycol 3350, 17 grams (cap filled to the indicated line)

OTC - 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

OTC - DO NOT USE

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

OTC - ASK DOCTOR/PHARMACIST

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

OTC - WHEN USING

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

OTC - PREGNANCY OR BREAST FEEDING

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

OTC - KEEP OUT OF REACH OF CHILDREN

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

OTC - QUESTIONS

Questions or comments?

1-800-540-3765

Manufactured by

Gericare Pharmaceuticals

1650 63rd Street, Brooklyn, NY 11204

Product of India

Issued: 10/2018

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 57896-490-30

Original

Prescription

Strength

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**

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

- Dissolves in any beverage
- Sugar Free

30 ONCE-DAILY DOSES

NET WT 17.9 OZ (510 g)

Original Prescription Strength

NDC 57896-490-30

Compare to the active ingredient in MiraLAX^{®*}



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

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



Sugar Free
30 ONCE-DAILY DOSES
NET WT 17.9 OZ (510 g)

1037414

Drug Facts ①

Active ingredient (in each dose)
 Polyethylene Glycol 3350, 17 grams
 (cap filled to the indicated line).....Osmotic Laxative

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

*This product is not manufactured or distributed by the owner of the registered trademark MiraLAX®

Code No.: KR/DRUGS/KTK/25/415/98

LOT: 1037/23

EXP: 1

No Varnish Zone

Drug Facts (continued) ②

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

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

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Drug Facts (continued) ③

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Inactive ingredients none

Questions or comments? 1-800-540-3765

Manufactured for:
 Gericare Pharmaceuticals
 1650 63rd Street, Brooklyn, NY 11204

Product of India
 Issued: 10/2018

510 g CAN

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-490
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
1	NDC:57896-490-30	510 g in 1 CAN; Type 0: Not a Combination Product	05/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	05/21/2019	

Labeler - Gericare Pharmaceuticals (611196254)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(57896-490) , MANUFACTURE(57896-490) , PACK(57896-490)

Revised: 6/2019

Gericare Pharmaceuticals