

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution

Gericare Pharmaceuticals

Polyethylene Glycol 3350, Powder for Solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 grams (cap filled to the indicated 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 or 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 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:
 - use once a day
 - 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
 - do not combine with the starch-based thickeners used for difficulty swallowing
 - ensure that the powder is fully dissolved before drinking
 - do not drink if there are any clumps
 - do not use more than 7 days
- children 16 years of age or under: ask a doctor

Other Information

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

Inactive ingredients

none

Questions or comments?

1-800-540-3765

Manufactured for:

Geri-Care Pharmaceuticals

1295 Townbin Ave. Lakewood, NJ 08701

Product of India

Issued: 07/2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Original

Prescription

Strength

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

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

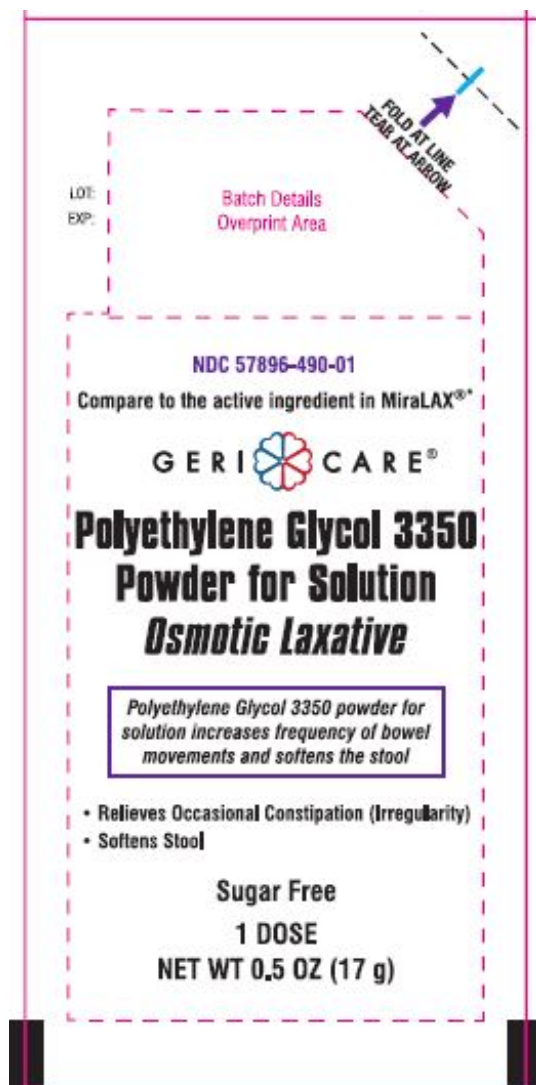
TAMPER-EVIDENT: DO NOT USE IF PRINTED FOIL SEAL UNDER CAP IS MISSING, OPEN OR BROKEN

- **Dissolves in any beverage**
- **Sugar Free**

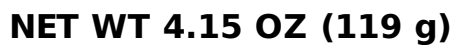
NDC 57896-490-01

1 DOSE

NET WT 0.5 OZ (17 g)



NET WT 0.5 OZ (17 g) Each





NDC 57896-490-14

14 ONCE-DAILY DOSES

NET WT 8.3 OZ (238 g)



NDC 57896-490-30

30 ONCE-DAILY DOSES

NET WT 17.9 OZ (510 g)



NDC 57896-490-45

45 ONCE-DAILY DOSES

NET WT 26.9 OZ (765 g)



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

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-490-07	119 g in 1 CAN; Type 0: Not a Combination Product	10/27/2022	
2	NDC:57896-490-14	238 g in 1 CAN; Type 0: Not a Combination Product	10/27/2022	
3	NDC:57896-490-30	510 g in 1 CAN; Type 0: Not a Combination Product	10/27/2022	
4	NDC:57896-490-45	765 g in 1 CAN; Type 0: Not a Combination Product	10/27/2022	
5	NDC:57896-490-03	30 in 1 CARTON	10/27/2022	
5	NDC:57896-490-01	17 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	10/27/2022	

Labeler - Gericare Pharmaceuticals (611196254)

Revised: 10/2022

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