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

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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
  - o 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**

**Ouestions 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

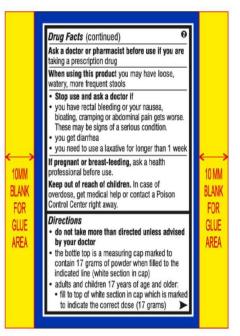
- Dissolves in any beverage
- Sugar Free

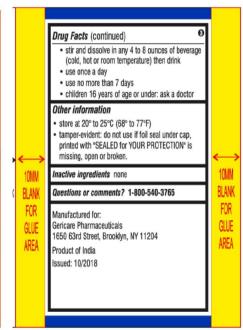
**30 ONCE-DAILY DOSES** 

NET WT 17.9 OZ (510 g)









# 510 g CAN

# **POLYETHYLENE GLYCOL 3350**

polyethylene glycol 3350 powder, for solution

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
<b>POLYETHYLENE GLYCOL 3350</b> (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		Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	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