

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

Major 44-726

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 g

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

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**
- adults and children 17 years of age and older:
 - use once a day
 - stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
 - do not combine with 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 is open or broken

Inactive ingredients

none

Questions or comments?

1-800-616-2471

Principal display panel

NDC 0904-6931-26

Compare to MiraLAX®

active ingredient*

MAJOR®

PEG3350

Polyethylene Glycol 3350

Powder for Oral Solution

Osmotic Laxative

- Relieves Occasional Constipation (Irregularity)
- Softens Stool

Dissolves in Any Beverage

Sugar Free

Unflavored

14 Once-Daily Doses
NET WT 0.5 OZ (17 g) Each

**TAMPER-EVIDENT: DO NOT USE IF
 FOIL IS OPEN OR BROKEN**

*This product is not manufactured or distributed by Bayer HealthCare LLC,
 owner of the registered trademark MiraLAX®.

Distributed by **MAJOR® PHARMACEUTICALS**
 Indianapolis, IN 46268

www.majorpharmaceuticals.com

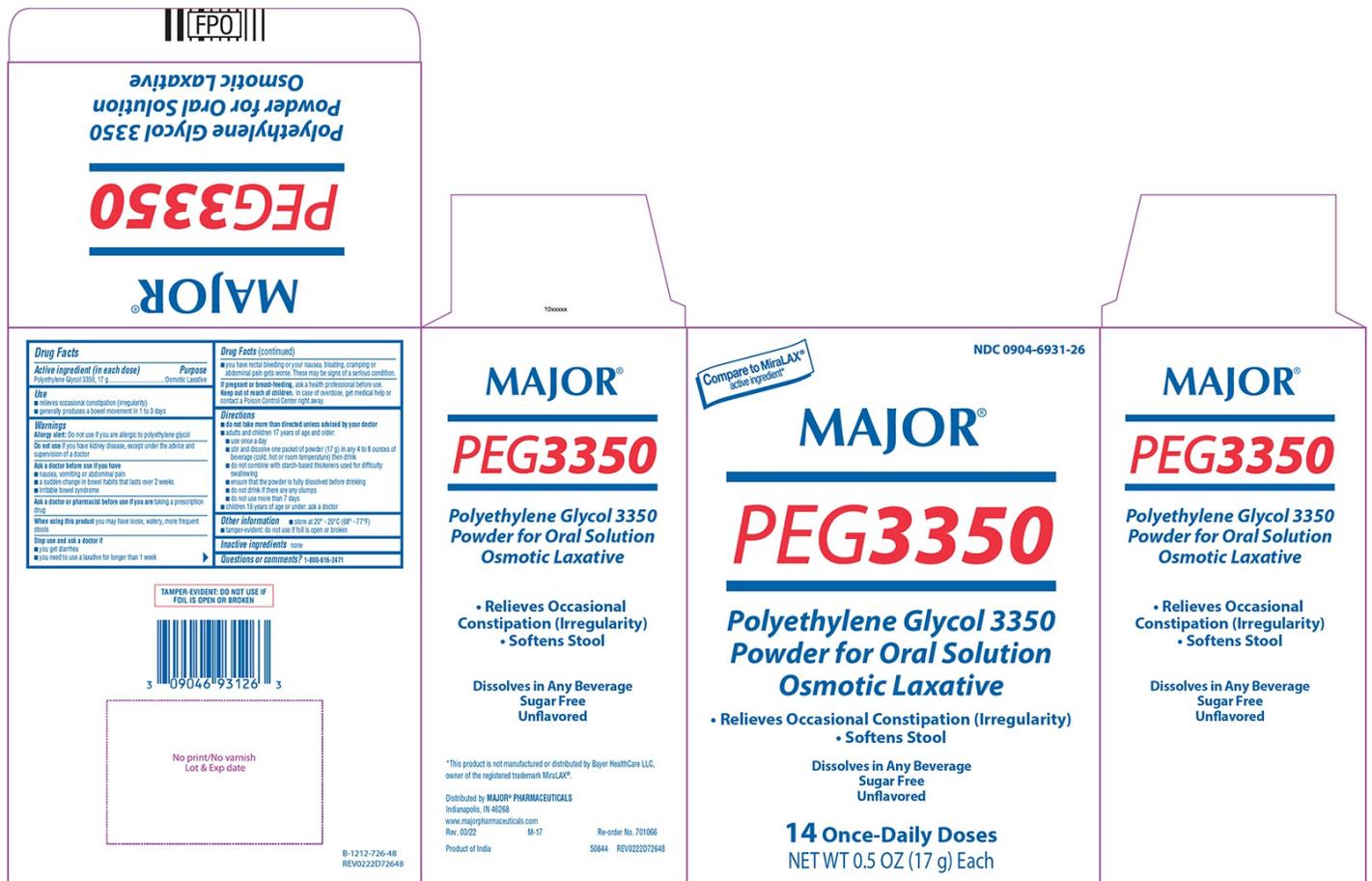
Rev. 03/22

M-17

Re-order No. 701066

Product of India

50844 REV0222D72648



Major 44-726

POLYETHYLENE GLYCOL 3350
 polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6931
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:0904-6931-86	17 g in 1 PACKET; Type 0: Not a Combination Product	06/30/2019	
2	NDC:0904-6931-26	14 in 1 CARTON	06/30/2019	
2		17 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0904-6931-76	30 in 1 CARTON	06/30/2019	
3		17 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:0904-6931-81	100 in 1 CARTON	06/30/2019	
4		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	06/30/2019	

Labeler - Major Pharmaceuticals (191427277)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-6931)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(0904-6931)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-6931)

Revised: 4/2024

Major Pharmaceuticals