POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, LAXATIVE-
polyethylene glycol 3350, nf powder for solution, laxative powder, for solution
LGM PHARMA SOLUTIONS, LLC

PEG 3350

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

Manufactured by:

LGM Pharma Solutions, LLC

Irvine, CA 92614

7116-0119-99-EC-PD

Rev. 01/2022

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 the top of white section in cap which is marked to indicate the correct dose (17g)
  - stir and dissolve 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 seal under cap, printed with “SEALED for YOUR PROTECTION” is missing, open or broken

Inactive ingredients

none

Questions or comments?

1-877-288-1495

Polyethylene Glycol 3350, NF increases frequency of bowel movements and

softens the stool.

Principal Display Panel

LGM PHARMA SOLUTIONS, LLC

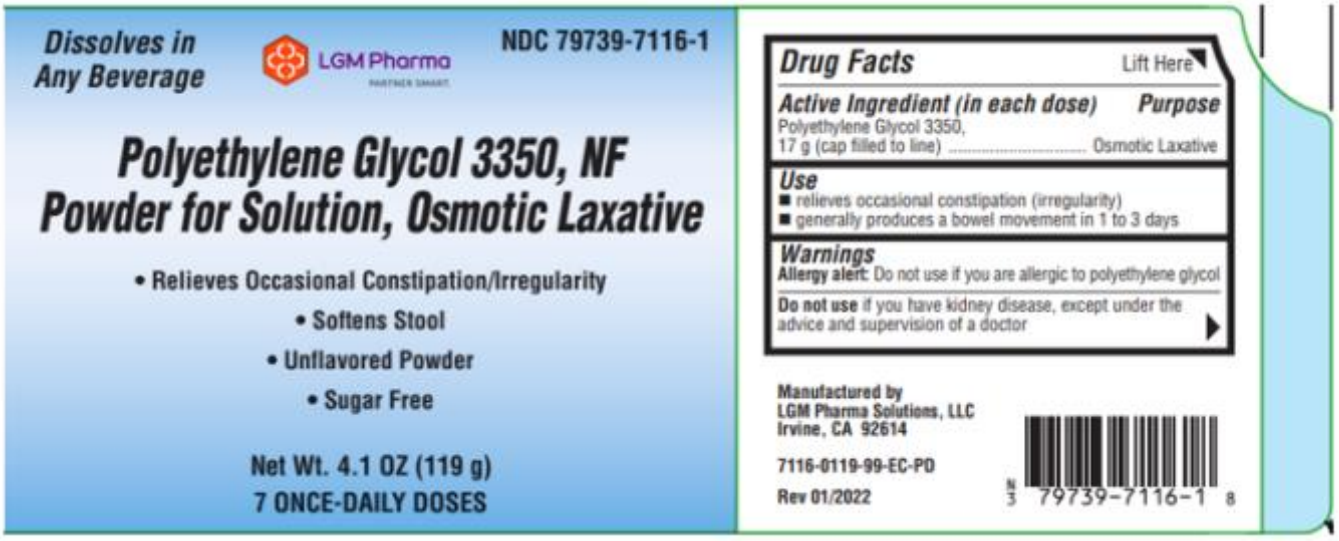
PRODUCT: Polyethylene Glycol 3350, NF Powder for Solution, Osmotic Laxative

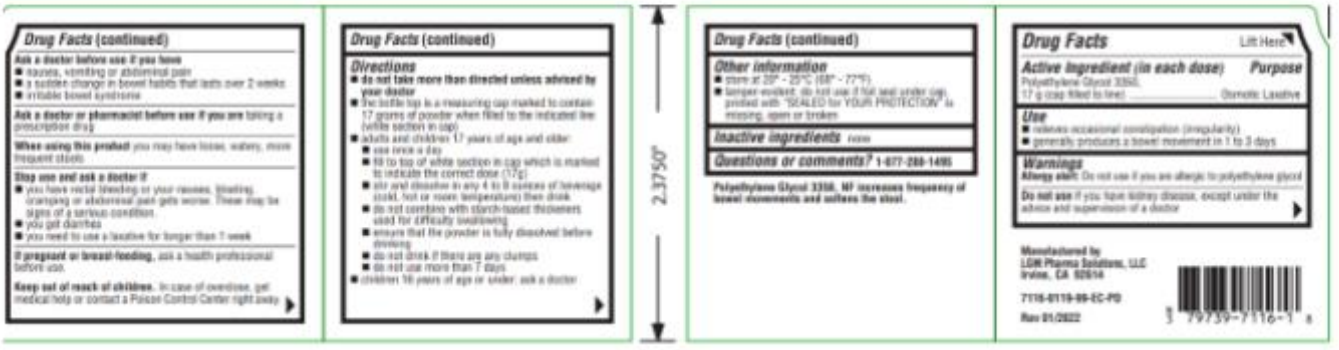
- **Relives Occasional Constipation/Irregularity**
- **Softens Stool**
- **Unflavored Powder**
- **Sugar Free**

Net Wt. 4.1 OZ (119g)

7 ONCE-DAILY DOSES

NDC: 79739-7116-1





Principal Display Panel

LGM PHARMA SOLUTIONS, LLC

PRODUCT: Polyethylene Glycol 3350, NF Powder for Solution, Osmotic Laxative

- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**
- **Unflavored Powder**
- **Sugar Free**

NDC: 79739-7116-2

Net Wt. 8.3 OZ (238g)

14 ONCE-DAILY DOSES

Principal Display Panel

LGM PHARMA SOLUTIONS, LLC

PRODUCT: Polyethylene Glycol 3350, NF Powder for Solution, Osmotic Laxative

- **Relives Occasional Constipation/Irregularity**
- **Softens Stool**
- **Unflavored Powder**
- **Sugar Free**

NDC: 79739-7116-3

Net Wt. 17.9 OZ (510g)

30 ONCE-DAILY DOSES

POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, LAXATIVE

polyethylene glycol 3350, nf powder for solution, laxative powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79739-7116
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 1 d

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:79739-7116-1	7 d in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009	
2	NDC:79739-7116-2	14 d in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009	
3	NDC:79739-7116-3	30 d in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	10/07/2009	

Labeler - LGM PHARMA SOLUTIONS, LLC (117549198)

Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549200	analysis(79739-7116) , label(79739-7116) , manufacture(79739-7116) , pack(79739-7116)

Revised: 1/2024 LGM PHARMA SOLUTIONS, LLC