

POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
Bryant Ranch Prepack

Polyethylene Glycol 3350, NF Powder for Oral Solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 g (cup filled to the indicated "17 GRAMS" 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**
- this product is supplied with a dosing cup marked to contain 17 grams of powder when filled to the indicated line
- adults and children 17 years of age and older:
 - use once a day
 - fill to the indicated "17 GRAMS" line on cup 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 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?

call: 1-800-367-3395

**Manufactured by:
LGM Pharma Solutions, LLC
Irvine, CA 92614**

**Distributed by:
Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037**

HOW SUPPLIED

NDC: 63629-8541-1: 238 g in a BOTTLE

Polyethylene Glycol 3350 Powder

GTIN 003629106424
Lot LOT123
Exp 07/10/2025
SN 1234567890

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Active ingredient (in each dose)	Product
Polyethylene Glycol 3350, 17 g (cup filled to the indicated "17 GRAMS" line).....	Osmotic Laxative
Uses	
•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.	
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Inactive Ingredients	
none	

NDC 63629-8541-1

**Polyethylene Glycol 3350, NF
(Powder for Solution,
Osmotic Laxative)**

17 gram/dose



238 grams

Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
LGM Pharma Solutions, LLC

6362985411

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63629-8541(NDC:51991-961)
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	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-8541-1	238 g in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2022	09/30/2024

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA090812	03/27/2019	09/30/2024

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-8541) , RELABEL(63629-8541)

Revised: 2/2024

Bryant Ranch Prepack