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

Polyethylene Glycol 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

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 (1-800-222-1222).

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 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 printed foil seal under cap is missing, open or broken

Inactive ingredients

none

Questions or comments?

1-800-719-9260

HOW SUPPLIED

NDC: 72162-2172-2: 238 g Powder for Solution NDC: 72162-2172-4: 510 g Powder for Solution

Polyethylene Glycol 3350 Powder #238



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Uses	
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NDC 72162-2172-2

Polyethylene Glycol 3350 **Powder for Solution Osmotic Laxative**

14 Once-Daily Doses



NET WT 8.3 OZ (238 g)

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



POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72162-2172(NDC:45802-868) **Route of Administration ORAL**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL **POLYETHYLENE** 17 g 3350 - UNII:G2M7P15E5P) GLYCOL 3350 in 17 g

Product Characteristics WHITE Color Score Shape Size Flavor **Imprint Code Contains**

Packaging Marketing End **Marketing Start Package Description Item Code Date Date** NDC:72162-238 g in 1 BOTTLE; Type 0: Not a Combination 01/23/2024 2172-2 Product NDC:72162-510 g in 1 BOTTLE; Type 0: Not a Combination 01/23/2024 2172-4 Product

Marketing Information					
Marketing	Application Number or Monograph	Marketing Start	Marketing End		
Category	Citation	Date	Date		

ANDA	ANDA090685	10/13/2009

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment					
Name	Address	ID/FEI	Business Operations		
Bryant Ranch Prepack		171714327	REPACK(72162-2172), RELABEL(72162-2172)		

Revised: 2/2024 Bryant Ranch Prepack