

RUGBY PEG 3350- polyethylene glycol 3350 powder, for solution
Rugby Laboratories

Rugby Laboratories 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

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 any clumps
- do not use no 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?

1-800-645-2158

Principal Display Panel

Rugby®

Compare to the active ingredient in MiraLAX®

PEG 3350

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

Relieves Occasional Constipation (Irregularity)

Softens Stool

Unflavored Grit Free Powder

NET WT 17.9 OZ (510 g)

30 Once-Daily Doses



NDC 0536-1052-27

Compare to the active ingredient in MiraLAX®*

PEG 3350

Polyethylene Glycol 3350 Powder for Solution

Osmotic Laxative

Relieves Occasional Constipation (Irregularity)
Softens Stool
Unflavored Grit Free Powder

NET WT 17.9 OZ (510 g)
30 Once-Daily Doses

: 30LD8 8T F2

Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.

Dissolves in Any Beverage

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).

Drug Facts (continued)

■ 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?
1-800-645-2158

• Sugar Free

*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of MiraLAX®.

Dist. by: RUGBY® LABORATORIES
Indianapolis, IN 46268
www.rugbylaboratories.com

Rev. 03/22 R-05 Re-order No. 370618



Directions: ...

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) ▶

: 306D & 8T 83

RUGBY PEG 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1052
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:0536-1052-24	238 g in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2015	
2	NDC:0536-1052-27	510 g in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2015	
3	NDC:0536-1052-84	850 g in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090685	01/05/2015	

Labeler - Rugby Laboratories (079246066)