

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

Rugby Laboratories PEG3350 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:
 - 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
 - use once a day
 - 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

Compare to MiraLAX® active ingredient

Unflavored Grit-Free Powder

PEG3350

Polyethylene Glycol 3350

Powder for Solution, Osmotic Laxative

Relieves Occasional Constipation (Irregularity)

Softens Stool

NET WT 17.9 OZ (510 g)

30 Once-Daily Doses

Compare to MiraLAX® active ingredient*

Rugby® NDC 0536-1052-27

Unflavored Grit-Free Powder

PEG3350

Polyethylene Glycol 3350
Powder for Solution, Osmotic Laxative

- Relieves Occasional Constipation (Irregularity)
- Softens Stool

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

30678 BT F1

Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool. Dissolves in Any Beverage

<p>Drug Facts</p> <p>Active ingredient (in each dose) Polyethylene Glycol 3350, 17 g (cap filled to line).....Osmotic Laxative</p> <p>Purpose</p> <p>Use</p> <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces a bowel movement in 1 to 3 days <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to polyethylene glycol</p> <p>Do not use if you have kidney disease, except under the advice and supervision of a doctor</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> nausea, vomiting or abdominal pain a sudden change in bowel habits that lasts over 2 weeks irritable bowel syndrome <p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p> <p>When using this product you may have loose, watery, more frequent stools</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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)</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 use once a day use no more than 7 days children 16 years of age or under: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> store at 20°-25°C (68°-77°F) tamper-evident: do not use if printed foil seal under cap is missing, open or broken <p>Inactive ingredients none</p> <p>Questions or comments? 1-800-645-2158</p> <ul style="list-style-type: none"> Sugar Free <p><small>*Rugby Laboratories PEG3350 is not manufactured or distributed by Bayer HealthCare, LLC distributor of MiraLAX®.</small></p> <p><small>Distributed by: Rugby Laboratories 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 www.rugbylaboratories.com R-05 REV 04/18 Re-Order No. 370618</small></p>
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30678 BT B1

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	Score
WHITE	
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)

Revised: 4/2019

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