

POLYETHYLENE GLYCOL-3350 - polyethylene glycol-3350 powder, for solution
Novel Laboratories, Inc.

Polyethylene Glycol 3350, Powder for Oral Solution

Drug Facts

OTC - ACTIVE INGREDIENT

Active Ingredient (in each dose).....Purpose

Polyethylene Glycol 3350, 17 g (cap filled to line).....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

OTC - DO NOT USE

Do not use if you have kidney disease, except under the advice and supervision of a doctor

OTC - ASK 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

OTC - ASK DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if you are taking a prescription drug

OTC - WHEN USING

When using this product you may have loose, watery, more frequent stools

OTC - STOP USE

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
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088

Drug Facts (continued)

OTC - PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

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.
- adults and children 17 years of age and older:
 - fill to top of line 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 INGREDIENT

Inactive Ingredients none

OTC - QUESTIONS

Questions or comments?

1-800-FDA-1088 (1-800-332-1088) or www.fda.gov

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Disolves in Any Beverage

Polyethylene Glycol 3350 Powder for Oral Solution
Laxative

7 ONCE-DAILY DOSES
 NET WT 4.1 OZ (119 g)

• Relieves Occasional Constipation
 • Softens Stool

Novel Laboratories, Inc. Somerset, NJ 08873

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

NDC 40032-312-07

Original Prescription Strength

40032-312-07 9

Drug Facts

Active Ingredient (in each dose)
 Polyethylene Glycol 3350, 17 g (cap filled to line)

Purpose
 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

PEEL HERE

Manufactured by:
 Novel Laboratories, Inc.
 Somerset, NJ 08873
 NDC 40032-312-07

Lot
 Exp.

<p>Drug Facts (continued)</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>Drug Facts (continued)</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 side effects occur. You may report side effects to FDA at 1-800-FDA-1088 <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 →</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 adults and children 17 years of age and older: <ul style="list-style-type: none"> fill to top of line 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>Drug Facts (continued)</p> <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-FDA-1088 (1-800-332-1088) or www.fda.gov</p>
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Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.

NDC 40032-312-08



Polyethylene Glycol 3350 Powder for Oral Solution

Laxative

- Relieves Occasional Constipation
- Softens Stool

NET WT 8.3 OZ (238 g) 14 ONCE-DAILY DOSES

Dissolves in Any Beverage

Drug Facts (continued)
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
<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 • adults and children 17 years of age and older: <ul style="list-style-type: none"> • fill to top of line 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
<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
Inactive Ingredients none
Questions or comments? 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov

Drug Facts
Active Ingredient (in each dose) Polyethylene Glycol 3350, 17 g (cap filled to line) Laxative
Purpose
Use
<ul style="list-style-type: none"> • 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
<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
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
<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 • side effects occur. You may report side effects to FDA at 1-800-FDA-1088

Lot
Exp.
NLE-312-08-00

40032-312-08 6

Novel Laboratories, Inc. Somerset, NJ 08873

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

NDC 40032-312-14

Original Prescription Strength

Polyethylene Glycol 3350 Powder for Oral Solution

Laxative

• Relieves Occasional Constipation
• Softens Stool

NET WT 17.9 OZ (510 g) 30 ONCE-DAILY DOSES

Drug Facts (continued)
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
• adults and children 17 years of age and older:
• fill to top of line in cap which is marked to indicate the correct dose (17 g)
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• 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-FDA-1088 (1-800-332-1088) or www.fda.gov

Drug Facts
Active Ingredient (in each dose) Polyethylene Glycol 3350, 17 g (cap filled to line) **Purpose** Laxative
Use
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Allergy alert: Do not use if you are allergic to polyethylene glycol
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Ask a doctor before use if you have
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• 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
• side effects occur. You may report side effects to FDA at 1-800-FDA-1088

Dissolves in Any Beverage

Lot Exp. NUB-312-14-00

40032-312-14 7

POLYETHYLENE GLYCOL-3350

polyethylene glycol-3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40032-312
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:40032-312-07	119 g in 1 BOTTLE		
2	NDC:40032-312-08	238 g in 1 BOTTLE		
3	NDC:40032-312-14	510 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091077	10/06/2009	

Labeler - Novel Laboratories, Inc. (793518643)

Contact	Address	Telephone Number	Email Address
Anu Radha Subramanian	Address: 400 Campus Drive City, State, Zip: Somerset, NJ, 08873 Country: USA	++1908-603-6000;ext=6002	ars@novellabs.net

Registrant - Novel Laboratories, Inc. (793518643)**Establishment**

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	MANUFACTURE, ANALYSIS, repack

Establishment

Name	Address	ID/FEI	Business Operations
Dow Chemical Company		801038019	api manufacture

Revised: 10/2009

Novel Laboratories, Inc.