

**POLYETHYLENE GLYCOL 3350 POWDER FOR SOLUTION- polyethylene glycol,
unspecified powder, for solution
VALLEY MEDICAL PRODUCTS, LLC**

Polyethylene Glycol 3350 Powder for Solution

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.

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 (17g)
- 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?

1-800-403-9832

Package Labeling:

<p>Drug Facts (continued)</p> <p>contain 17 grams of powder when filled to the indicated line (white section in cap)</p> <ul style="list-style-type: none"> adults and children 17 years of age and older: <ul style="list-style-type: none"> use once a day fill to top of white section in cap which is marked to indicate the correct dose (17g) 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 	<p>10 MM BLANK GLUE AREA</p>	<p>Drug Facts</p> <p>Active ingredient (in each dose) Purpose Polyethylene Glycol 3350, 17 g (cap filled to line).....Osmotic Laxative</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>This product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc., the distributor of MiraLax®</p> <p>Manufactured for, ©Copyright & Distributed by Valley Medical Products, LLC, Jacksonville, FL 32224 USA. All rights reserved.</p> <p>10xxxxx Cash No.: KRDRUGS/KTK/25/415/98 LOT: 3 7 6 4 7 0 1 0 6 9 6 9 5 EXP: 1</p> <p>No Yamashita Logo</p>
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55 MM

104 MM

<p>10 MM BLANK GLUE AREA</p>	<p>Drug Facts (continued)</p> <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, 	<p>Drug Facts (continued)</p> <p>bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.</p> <ul style="list-style-type: none"> 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.</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
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104 MM



<p>10 MM BLANK GLUE AREA</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 <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? 1-800-403-9832</p>	<p>10 MM BLANK GLUE AREA</p>
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55 MM

Compare to
MiraLAX®*



NDC 76470-069-69

Original Prescription Strength



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

*Polyethylene Glycol 3350 powder for solution increases
frequency of bowel movements and softens the stool*

- Relieves Occasional Constipation (Irregularity)
- Softens Stool • Unflavored • Sugar Free • Dissolves in Any Beverage

**Tamper-evident: do not use if
printed foil seal under cap is
missing, open or broken**

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

10xxxx

Valley Medical Products, LLC

POLYETHYLENE GLYCOL 3350 POWDER FOR SOLUTION
polyethylene glycol, unspecified powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76470-069
Route of Administration	TOPICAL		

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76470-069-69	238 g in 1 JAR; Type 0: Not a Combination Product	10/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	10/01/2025	

Labeler - VALLEY MEDICAL PRODUCTS, LLC (969389407)

Registrant - Strides Pharma Science Limited (918513263)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	manufacture(76470-069)

Revised: 10/2025

VALLEY MEDICAL PRODUCTS, LLC