

POLYETHYLENE GLYCOL 3350- instalax polyethylene glycol 3350 powder, for solution

Sun Pharmaceutical Industries, Inc.

Instalax TM Polyethelene Glycol 3350, Powder for Solution, Osmotic Laxative

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 the 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 (17 grams)
 - 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° to 25°C (68° to 77°F)
- tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Inactive ingredients

none

Questions or comments?

1-877-244-9825

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

Manufactured in India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

POLYETHYLENE GLYCOL, 3350 - 765 g - 45 Doses - Container Label [Front]

NDC 51672-2104-3

ohm

LABORATORIES INC.

a SUN PHARMA company

Original
Prescription Strength

1168459 0825

InstaLax™

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)

- Dissolves in Any Beverage
- Softens Stool • Unflavored
- Sugar Free

45 ONCE-DAILY DOSES

NET WT 26.9 oz (765 g)

TAMPER-EVIDENT: DO NOT USE IF PRINTED FOIL SEAL
UNDER CAP IS MISSING, OPEN OR BROKEN

Instalax Polyethylene Glycol 3350 (765G) Container Label - Back

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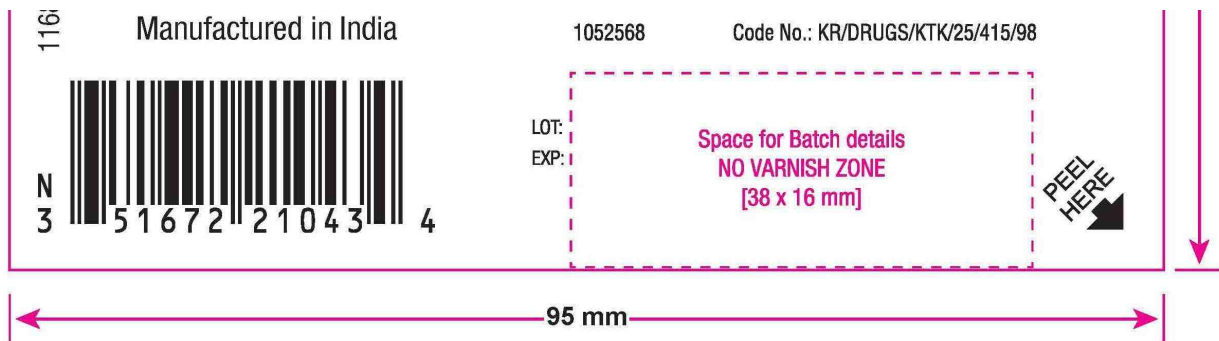
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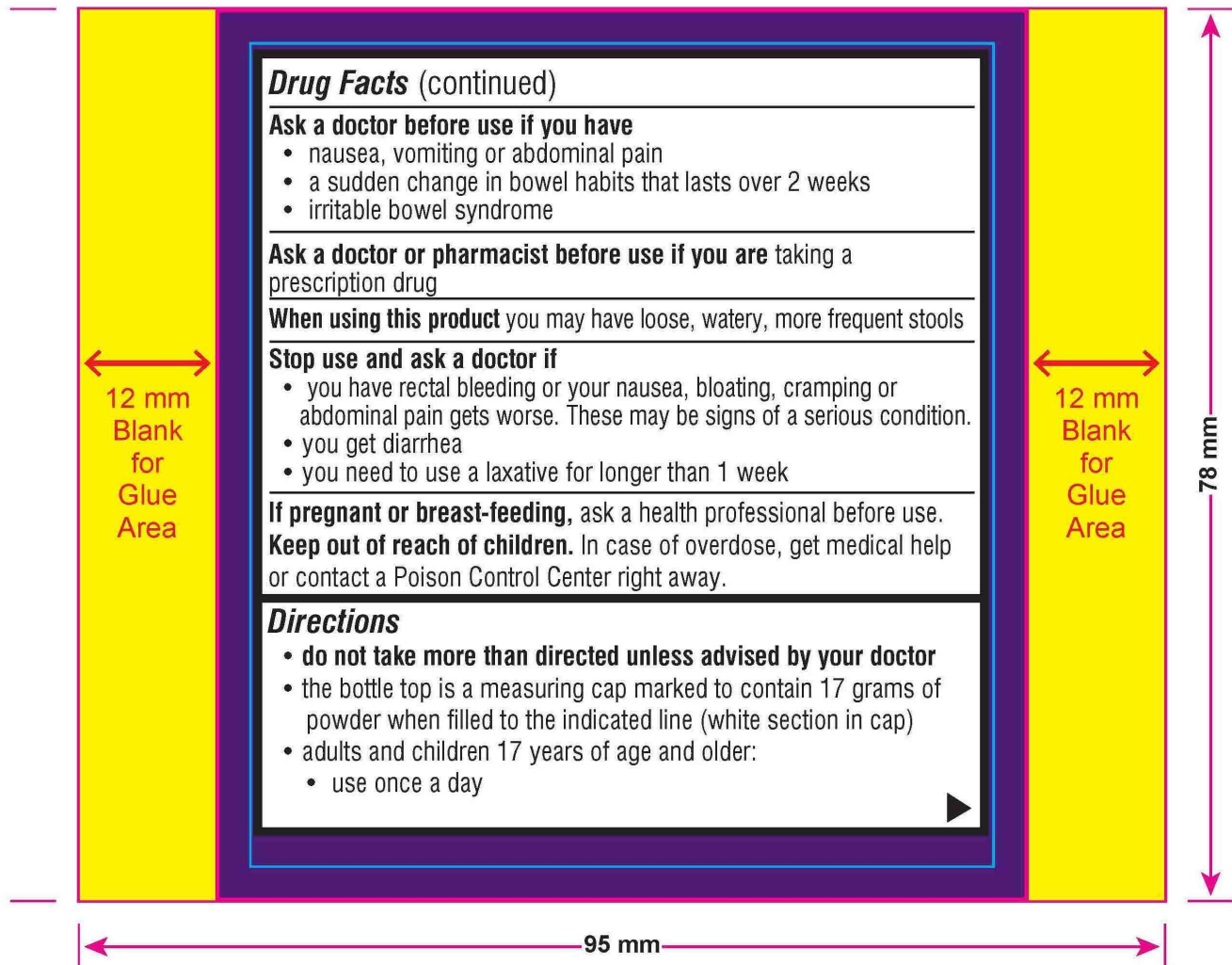
Ohm Laboratories Inc.

New Brunswick, NJ 08901

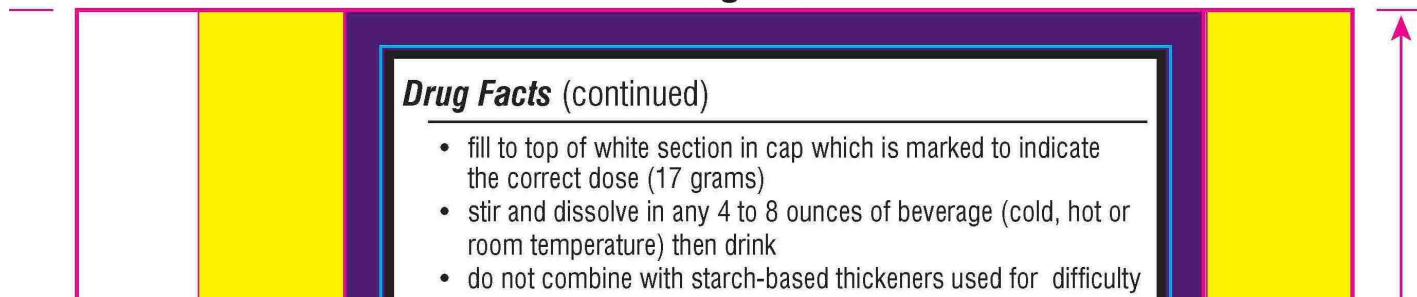
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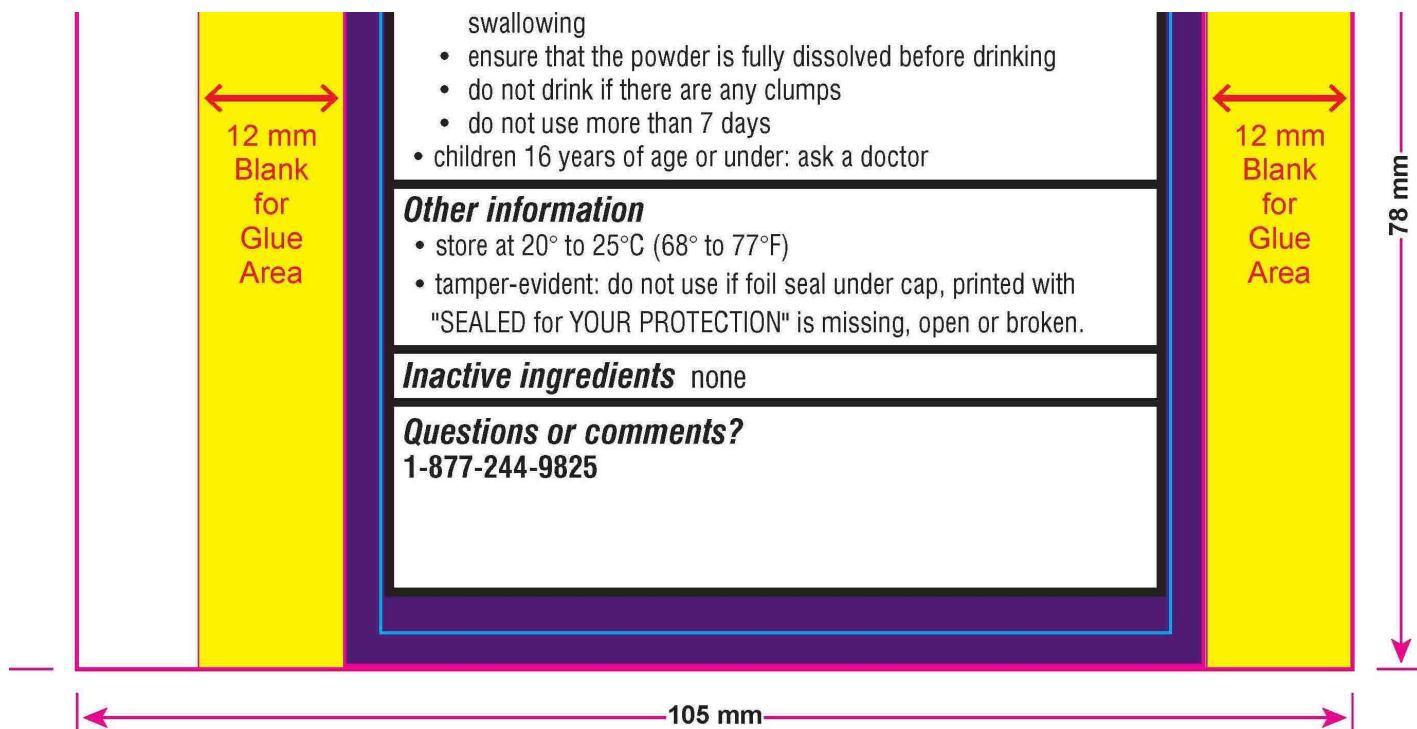


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POLYETHYLENE GLYCOL 3350

instalax polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2104
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 (Colorless upon dissolution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2104-3	765 g in 1 CAN; Type 0: Not a Combination Product	10/09/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	10/09/2025	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	analysis(51672-2104) , manufacture(51672-2104) , pack(51672-2104)

Revised: 11/2025

Sun Pharmaceutical Industries, Inc.