

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution

Strides Pharma Inc

Polyethelene Glycol 3350, Powder for Solution

Polyethylene Glycol 3350, Powder for Solution

Drug Facts

Active ingredient (in each dose) (Can only)

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

Purpose

Osmotic Laxative

Active ingredient (in each dose) (Packet Only)

Polyethylene Glycol 3350, 17 g

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 (Can Only)

- **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 are any clumps
 - do not use more than 7 days
- children 16 years of age or under: ask a doctor

Directions (Packet Only)

- **do not take more than directed unless advised by your doctor**
- adults and children 17 years of age and older:
 - use once a day
 - stir and dissolve one packet of powder (17 g) 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 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

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

Manufactured by:

Strides Pharma Science Limited

Bengaluru – 5562106, India.

Distributed by

Strides Pharma Inc.

East Brunswick, NJ 08816

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

10

Packets

NDC 59556-762-01

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**

TAMPER-EVIDENT: DO NOT USE IF FOIL IS OPEN OR BROKEN

- ***Unflavored***
- ***Sugar Free***
- ***Dissolves in Any Beverage***

10 ONCE-DAILY DOSES

10 PACKETS

NET WT 0.5 OZ (17g) EACH



10s carton

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

24

Packets

NDC 59556-762-02

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**

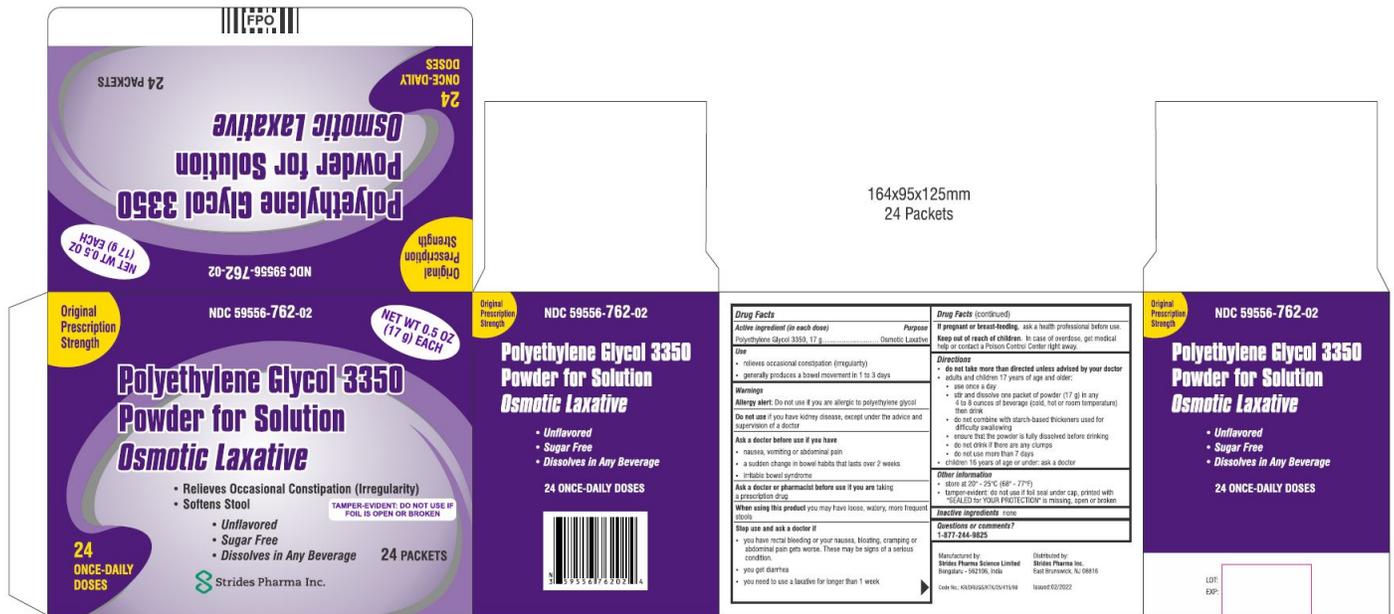
TAMPER-EVIDENT: DO NOT USE IF FOIL IS OPEN OR BROKEN

- **Unflavored**
- **Sugar Free**
- **Dissolves in Any Beverage**

24 ONCE-DAILY DOSES

24 PACKETS

NET WT 0.5 OZ (17g) EACH



24s carton

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 59556-762-00

Original

Prescription

Strength

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**

TAMPER-EVIDENT: DO NOT USE IF FOIL IS OPEN OR BROKEN

- **Unflavored**
- **Sugar Free**
- **Dissolves in Any Beverage**

1 DOSE

NET WT 0.5 OZ (17 g)

NET WT 4.15 OZ
(119 g)

NDC 59556-762-03

4642

Polyethylene Glycol 3350
Powder for Solution
Osmotic Laxative

Original
Prescription
Strength

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

1046896

7
ONCE-DAILY
DOSES

 Strides Pharma Inc.

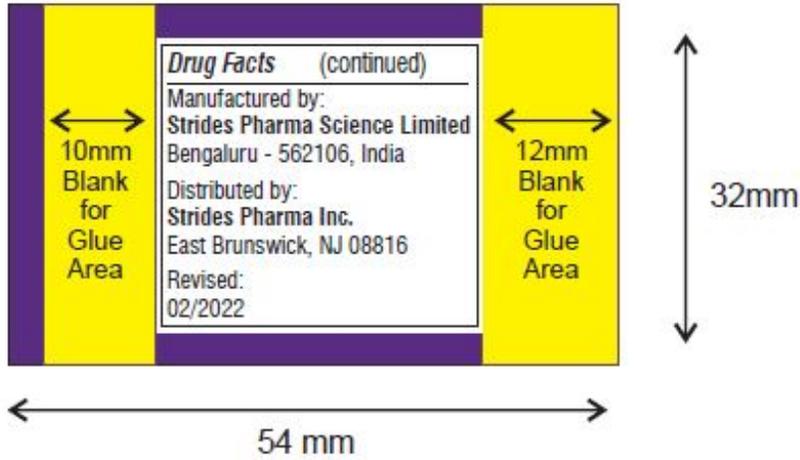
TAMPER-EVIDENT: DO NOT
USE IF PRINTED FOIL SEAL
UNDER CAP IS MISSING,
OPEN OR BROKEN

54 x 32 mm

119 g CAN - FRONT

**UNWINDING
DIRECTION** →

BASE LABEL



119 g BACK [CAN]

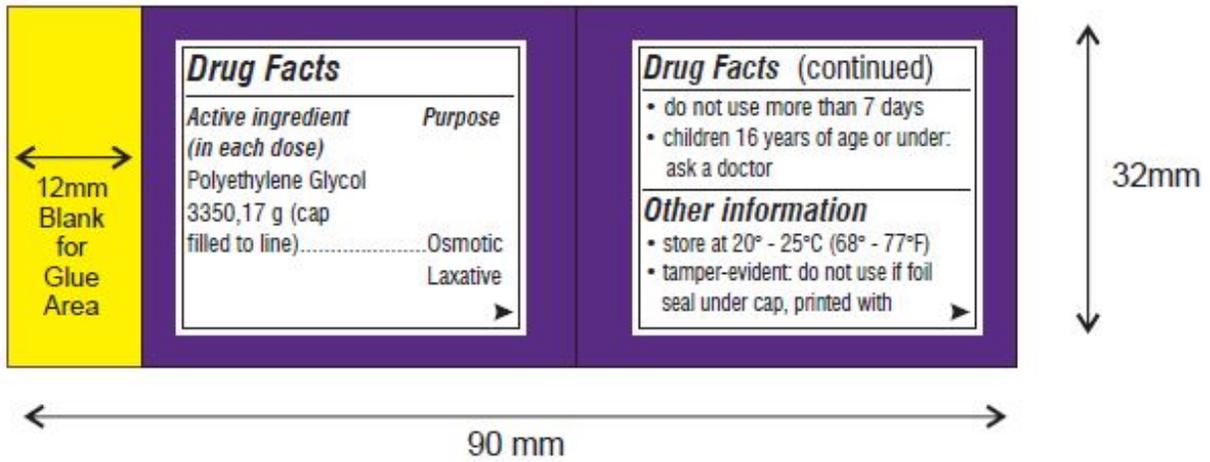
PAGE 12

PAGE 01



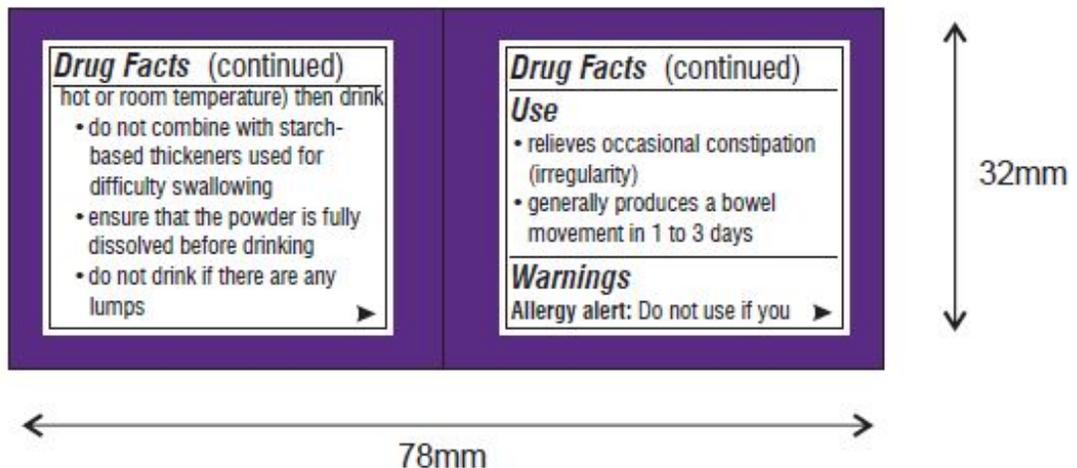
PAGE 02

PAGE 11



PAGE 10

PAGE 03



119g BACK [CAN]

PAGE 04

PAGE 09

<p>Drug Facts (continued)</p> <p>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 	<p>Drug Facts (continued)</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,
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32mm

78mm

PAGE 08

PAGE 05

<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 17grams of powder when filled to the indicated line (white section in cap) 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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</p>
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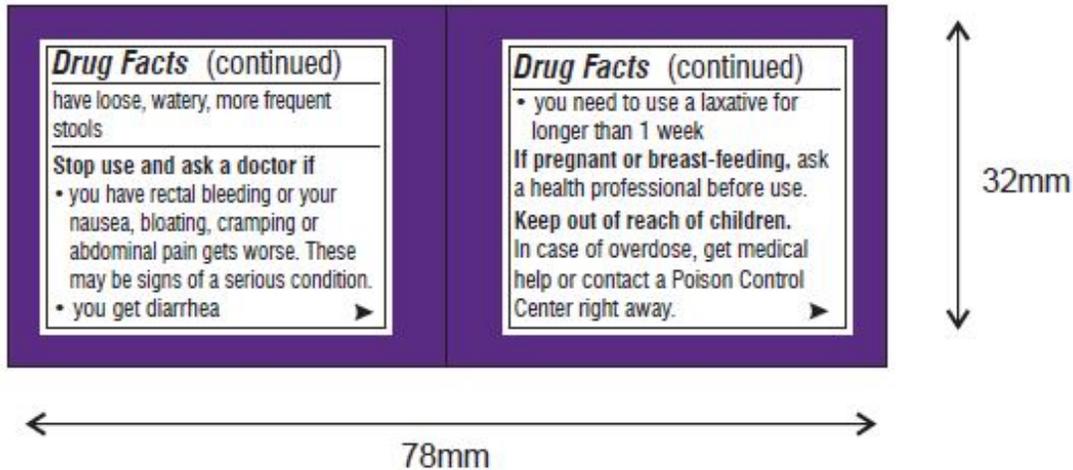
32mm

78mm

119g BACK [CAN]

PAGE 06

PAGE 07



119g BACK [CAN]

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 59556-762-04

Original

Prescription

Strength

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**

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

- **Unflavored**
- **Sugar Free**
- **Dissolves in Any Beverage**

14

ONCE-DAILY

DOSES

NET WT 8.3 OZ (238 g)



62 x 55 mm

238 G CAN - FRONT

PAGE 04

PAGE 01

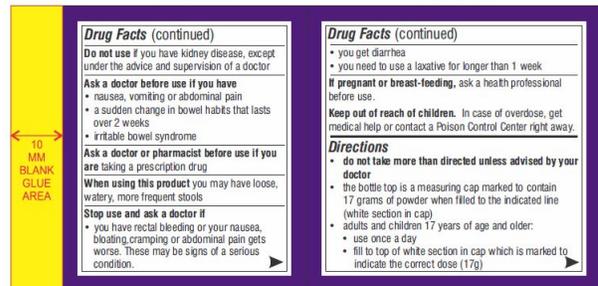
PAGE 02

PAGE 03



114 MM

55 MM



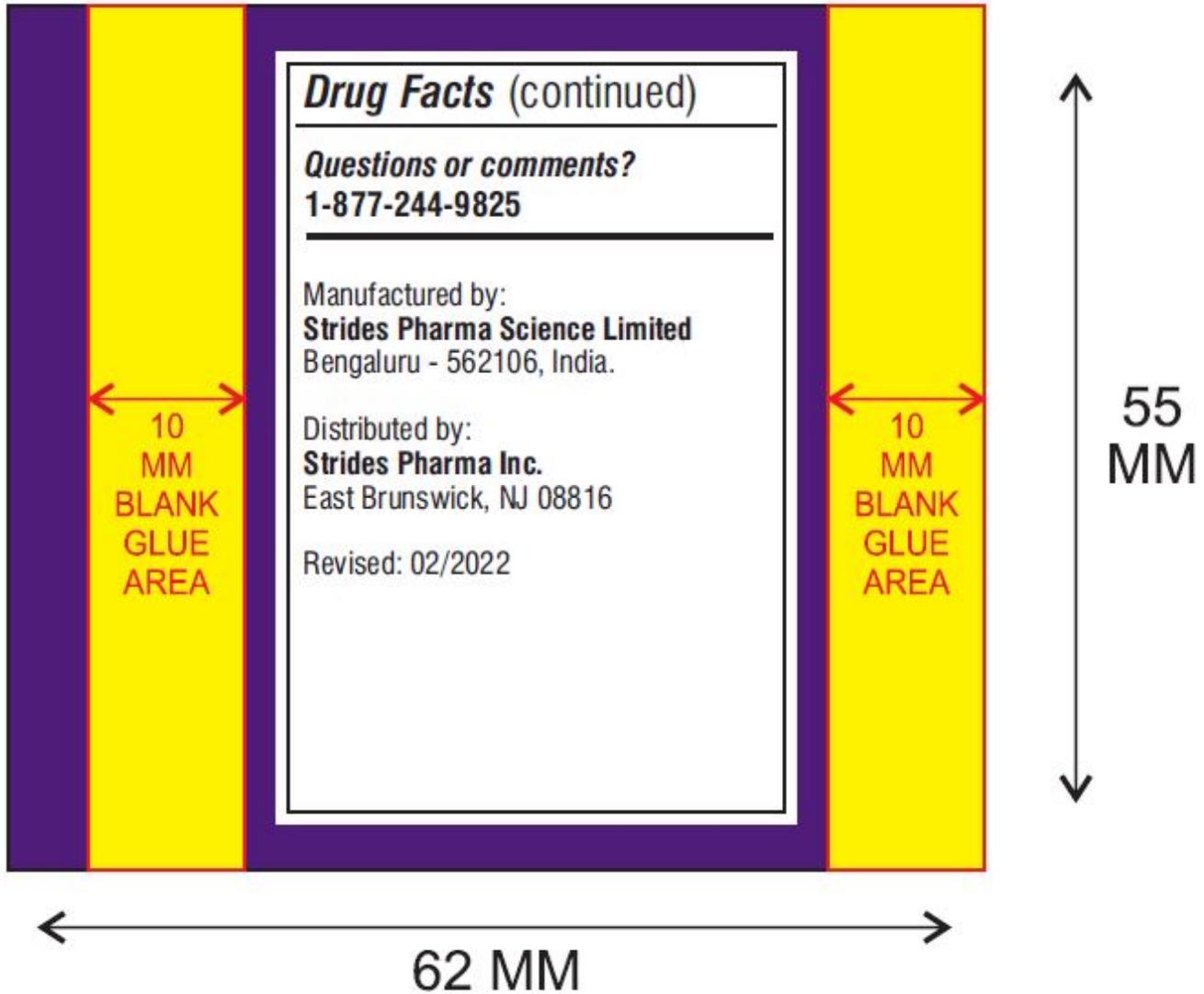
114 MM

55 MM

238 G CAN - BACK

**UNWINDING
DIRECITON** 

BASE LABEL



238 G CAN - BACK

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 59556-762-05

Original

Prescription

Strength

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**

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

- ***Unflavored***
- ***Sugar Free***
- ***Dissolves in Any Beverage***

30

ONCE-DAILY

DOSES

NET WT 17.9 OZ (510 g)



82 x 78 mm

510 g CAN - FRONT

PAGE 01



77 MM

PAGE 02



77 MM

UNWINDING
DIRECTION

BASE LABEL



82 MM

510 g CAN - BACK

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-762
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:59556-762-04	238 g in 1 CAN; Type 0: Not a Combination Product	08/25/2016	
2	NDC:59556-762-03	119 g in 1 CAN; Type 0: Not a Combination Product	08/25/2016	
3	NDC:59556-762-05	510 g in 1 CAN; Type 0: Not a Combination Product	08/25/2016	
4	NDC:59556-762-02	24 in 1 CARTON	08/25/2016	
4	NDC:59556-762-00	17 g in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:59556-762-01	10 in 1 CARTON	08/25/2016	
5	NDC:59556-762-00	17 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	08/25/2016	

Labeler - Strides Pharma Inc (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-762) , MANUFACTURE(59556-762) , PACK(59556-762)

Revised: 2/2022

Strides Pharma Inc