

MIRALAX ORANGE FLAVOR- polyethylene glycol 3350 powder, for solution
Bayer HealthCare LLC.

MiraLAX[®] Orange Flavor

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 of 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 you nausea, bloating or 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(1-800-222-1222).

Directions (Bottle 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

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

natural and artificial orange flavor, sucralose

Questions or comments?

1-800-MiraLAX (1-800-647-2529)

PRINCIPAL DISPLAY PANEL - 7 Dose Bottle

MiraLAX ®

Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

Relieves Occasional Constipation/Irregularity

Softens Stool

Grit-Free Powder

Sugar-Free & Dye-Free

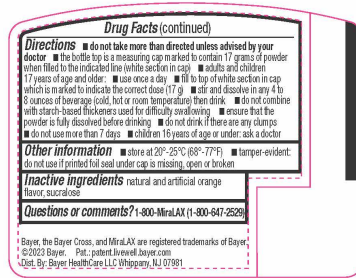
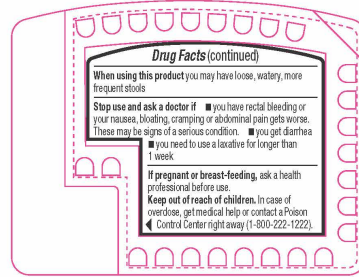
ORANGE FLAVOR

7 ONCE-DAILY DOSES

NET WT 4.1 OZ (119 g)

Bayer





MIRALAX ORANGE FLAVOR

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0122
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL	POLYETHYLENE	17 g

3350 - UNII:G2M7P15E5P)

GLYCOL 3350

in 17 g

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	white (White or almost white solid with a waxy or paraffin-like appearance)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0122-2	119 g in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2023	
2	NDC:11523-0122-1	238 g in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090685	09/15/2023	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 10/2023

Bayer HealthCare LLC.