LEADER CLEARLAX- polyethylene glycol 3350 powder, for solution Cardinal Health 110, LLC. dba Leader

Cardinal Health ClearLax® 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. (1-800-222-1222)

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:
- 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
- ensure that the powder is fully dissolved before drinking
- do not drink if there any clumps
- 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?

1-800-719-9260

Principal Display Panel

Grit-Free | Unflavored Powder

ClearLax®

Polyethylene Glycol 3350

Powder for Solution, Osmotic Laxative

COMPARE TO MIRALAX® active ingredient

Relieves Occasional Constipation/Irregularity

Softens Stool

7 ONCE-DAILY DOSES



LEADER CLEARLAX

polyethylene alycol 3350 powder, for solution

polyetriylerie giycor 3330 powder, for solution							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Sour	ce)	NDC:70000	-0415		
Route of Administration	ORAL						
Active Ingredient/Active Moiety							
Ingredient Name Basis of S				Strength	Strength		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)			POLYETHYLI		17 g		
3330 OMI.GZP171 13L31 /			GLICUL 333	50	in 17 g		

Product Characteristics					
Color	WHITE	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:70000- 0415-1	119 g in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2018				
2	NDC:70000- 0415-3	510 g in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2019				
3	NDC:70000- 0415-2	238 g in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2019				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA090685	12/27/2018				

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

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