EQUALINE CLEARLAX- polyethylene glycol 3350 powder, for solution United Natural Foods, Inc. dba UNFI

SuperValu Inc. 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:
- 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

none

Questions or comments?

1-855-423-2630

Principal Display Panel

EQUALINE[®]

compare to MiraLAX® active ingredient

clearlax®

polyethylene glycol 3350

powder for solution

osmotic laxative

- relieves occasional constipation/irregularity
- softens stool
- unflavored grit free powder

30 ONCE-DAILY DOSES

NET WT 17.9 OZ (510g)

EQUALINE®

compare to MiraLAX®

active ingredient*

clearlax®

polyethylene glycol 3350 powder for solution osmotic laxative

- relieves occasional constipation/ irregularity
- softens stool
- unflavored grit free powder

30 ONCE-DAILY DOSES

NET WT 17.9 OZ (510g)

: 306D8 EL F4

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

Dissolves in Any Beverage

Drug Facts

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Purpose

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

......Osmotic Laxative

Use ■ relieves occasional constipation (irregularity)
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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

Drug Facts (continued)

■ 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

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Inactive ingredients none

Questions or comments?





EQUALINE CLEARLAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-306

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL
3350 - UNII:G2M7P15E5P)

Basis of Strength
POLYETHYLENE
GLYCOL 3350

in 17 g
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:41163-306- 01	119 g in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009		
2	NDC:41163-306- 02	238 g in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009		
3	NDC:41163-306- 03	510 g in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009		
4	NDC:41163-306- 52	10 in 1 CARTON	08/10/2012	11/25/2015	
4		17 g in 1 POUCH; Type 0: Not a Combination Product			

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
Category ANDA	Citation ANDA090685	Date 10/07/2009	Date

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

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