

**CLEARLAX- polyethylene glycol powder, for solution**  
**Rebel Distributors Corp**

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**Drug Facts**

**Active ingredient**

Polyethylene Glycol

**Purpose**

Use(s)

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

**Keep Out of Reach of Children**

**Uses**

Use(s)

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

**Warnings**

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

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

## **Directions**

Directions

- do not take more than directed unless advised by your doctor
- adults and children 17 years of age and older:
  - stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
  - use once a day
  - use no more than 7 days
- children 16 years of age or under: ask a doctor
- 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
  - use once a day
  - use no more than 7 days
- children 16 years of age or under: ask a doctor

Other information

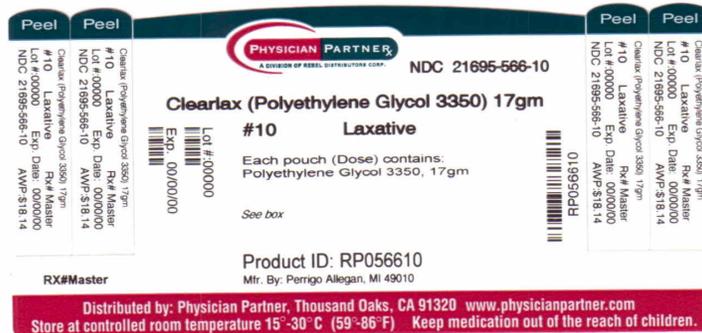
- store at 20°-25°C (68°-77°F)
- tamper-evident: do not use if printed foil pouch is open or broken (Pouch Carton Only)
- tamper-evident: do not use if printed foil seal under cap is missing, open or broken (Label Only)

## **Inactive ingredients**

Inactive ingredients

none

## **Package/Label Principal Display Panel**



## CLEARLAX

polyethylene glycol powder, for solution

### Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:21695-566(NDC:0 113-0306) |
| <b>Route of Administration</b> | TOPICAL        |                           |                               |

### 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     |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:21695-566-10 | 10 in 1 BOX         |                      |                    |

### Marketing Information

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

**Labeler** - Rebel Distributors Corp (118802834)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Rebel Distributors Corp |         | 118802834 | RELABEL, REPACK     |