

**PEDIATRIC GLYCERIN LAXATIVE - glycerin suppository**  
**Cardinal Health, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts Active ingredient**

(per suppository)

Glycerin, USP 1 g

**Purpose**

Laxative

**Keep out of reach of children.**

**Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1212).**

**Use**

For relief of occasional constipation

**Warnings**

**For rectal use only.** May cause rectal discomfort or burning sensation.

**Ask a doctor before use if your child has**

- abdominal pain, nausea, or vomiting.
- a sudden change in bowel habits lasting more than 2 weeks.
- if you have already used a laxative for a week

**Stop use and ask a doctor if your child has**

rectal bleeding or fails to have a bowel movement within one hour of using this product. This may indicate a serious condition.

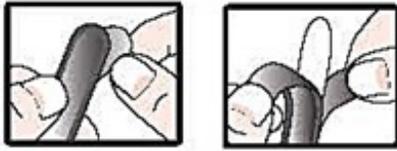
**If pregnant or breastfeeding,**

ask a doctor before use.

**Directions**

- **Children 2 to under 6 years:**
- detach 1 suppository from the strip; remove wrapper before inserting into the rectum as follows:
- hold suppository with pointed end up
- carefully separate tabs with fingernail
- slowly pull apart by pulling tabs down on both sides
- remove suppository from wrapper

- Carefully insert one suppository well into the rectum and retain for 15 minutes
- It need not melt completely to produce laxative action
- Generally produces bowel movement in 15 minutes to 1 hour
- Do not exceed one suppository daily unless directed by a doctor
- **Children under 2 years: consult a doctor**



### **Inactive ingredients**

sodium stearate, purified water

### **Other information**

- Store container tightly closed
- Keep from excessive heat

### **Pediatric Glycerin Suppository Label**

**NDC 49781-080-25**

**LEADER®**

**Compare to Fleet® active ingredient\***

**Pediatric Glycerin Suppositories  
Laxative**

SATISFACTION GUARANTEED

25 Pediatric Size

**TAMPER-EVIDENT: FOR YOUR SAFETY , SUPPOSITORIES ARE PACKED IN TAMPER-EVIDENT SEALED WRAPPER. DO NOT USE IF WRAPPER IS TORN OR OPEN**

E-Z Open Wrapper

Distributed by Cardinal Health, Inc.  
Dublin, Ohio 43017  
CIN 4873303  
www.myleader.com  
1-800-200-6313

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This product is not manufactured or distributed by C.B. Fleet Co. Inc., owner of the registered trademark Fleet®.

**LEADER®**

**Pediatric Glycerin Suppositories**  
*Laxative*

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- if you have already used a laxative for a week
- Stop use and ask a doctor if your child has rectal bleeding or fails to have a bowel movement within one hour of using this product. This may indicate a serious condition.
- If pregnant or breastfeeding, ask a doctor before use.
- Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1212).

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**Pediatric Glycerin Suppositories**  
*Laxative*

**Compare to Fleet®**  
active ingredient\*

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## PEDIATRIC GLYCERIN LAXATIVE

glycerin suppository

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49781-080
<b>Route of Administration</b>	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	1 g

### Inactive Ingredients

Ingredient Name	Strength
SODIUM STEARATE (UNII: QU7E2XA9TG)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-080-25	25 in 1 BOX		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/01/2014	

**Labeler** - Cardinal Health, Inc. (097537435)

**Registrant** - Acino Products LLC (019385518)

## Establishment

Name	Address	ID/FEI	Business Operations
Acino Products LLC		019385518	manufacture(49781-080)

Revised: 3/2014

Cardinal Health, Inc.