

ADULT 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.

Drug Facts Active ingredient

(per suppository)

Glycerin, USP 2 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 you have

- abdominal pain, nausea or vomiting.
- a sudden change in bowel habits lasting for more than 2 weeks.
- already used a laxative for more than 1 week.

Stop use and ask a doctor

if you have rectal bleeding or fail to have a bowel movement after using a laxative. This may indicate a serious condition.

If pregnant or breastfeeding,

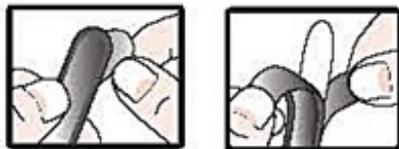
ask a doctor before use.

Directions

Single Daily dosage: 1 suppository or as directed by a doctor

- Adults and children 6 years and over:
- detach 1 suppository from the strip; remove the 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
- insert one suppository well up into the rectum
- children 2 to 6 years use Leader Pediatric Glycerin Suppositories
- children under 2 years of age ask a doctor



Inactive ingredients

sodium stearate, purified water

Other information

- This product usually produces a bowel movement in 1/4 to 1 hour
- Store container tightly closed
- Keep from excessive heat

Adult Glycerin Suppositories Label

NDC 49718-081-25

Leader®

Compare to Fleet® active ingredient*

Glycerin Suppositories

Laxative

SATISFACTION GUARANTEED

25 Adult 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, OH 43017 CIN # 4866216
www.myleader.com 1-800-200-6313

ALL LEADER® Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

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ADULT GLYCERIN LAXATIVE

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-081
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM STEARATE (UNII: QU7E2XA9TG)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:49781-081-25	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(49781-081)

Revised: 3/2014

Cardinal Health, Inc.