

PEDIA-LAX- glycerin suppository
C.B. Fleet Company, 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.

Pedia-Lax Glycerin Suppositories

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Active Ingredient

Glycerin 1 g

Purpose

Hyperosmotic Laxative

Uses

- for relief of occasional constipation
- this product usually produces bowel movement $\frac{1}{4}$ to 1 hour

Warnings

□ **For rectal use only**

May cause rectal discomfort or a burning sensation.

Ask a doctor before using any laxative if child has

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

Stop use and consult a doctor if child has

- rectal bleeding
- no bowel movement within 1 hour of using this product

These symptoms may indicate a serious condition.

Keep out of reach of children

to prevent accidental ingestion.

□ **If swallowed, get medical help or contact a Poison Control Center right away.**

Directions

Single Daily Dosage (per 24 hours)

children 2 to under 6 years	1 suppository or as directed by a doctor
children under 2 years	ask a doctor

Insert suppository well up into rectum. To produce laxative action suppository is designed to dissolve only partially, which may not be noticeable.

Other information

- Store container tightly closed
- Keep away from excessive heat
- Mouth of jar sealed for safety. If foil imprinted with green Fleet® emblem is missing or torn, do not use.

Inactive ingredients

aloe vera gel (decolorized), edetate disodium, purified water, sodium hydroxide, stearic acid

Questions?

1-866-255-6960 or www.pedia-lax.com

PRINCIPAL DISPLAY PANEL

Pedia-Lax

Glycerin Suppositories

Laxative

12 suppositories



PEDIA-LAX

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0081
Route of Administration	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
ALOE (UNII: V5VD430 YW9)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0081-12	12 in 1 JAR; Type 0: Not a Combination Product	03/01/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/01/2008	

Labeler - C.B. Fleet Company, Inc. (003119054)

Revised: 4/2020

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