

PEDIA-LAX- glycerin liquid
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.

Active Ingredient (in each 2.7 mL average delivered dose)

Glycerin 2.8 g, Hyperosmotic Laxative

Uses

- For relief of occasional constipation
- This product generally produces bowel movement in 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 the 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
- if constipation continues after one week of use, contact your child's doctor

Stop using this product and consult a doctor if the 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

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	consult a doctor

Other Information

- carton sealed for safety. If seal with Fleet emblem on bottom flap or top flap is broken or missing, do not use.

Inactive Ingredients

edetate disodium, purified water

Questions?

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



PEDIA-LAX

glycerin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0190
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2.8 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0190-12	4 in 1 CARTON; 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)

Establishment			
Name	Address	ID/FEI	Business Operations
C.B. Fleet Company, Inc.		003119054	manufacture(0132-0190)

Revised: 10/2017

C.B. Fleet Company, Inc.