# 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.

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## Pedia-Lax Liquid Glycerin Suppositories

### Active ingredient (in each 2.7 mL average delivered dose)

Glycerin 2.8 g

#### Purpose

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 (1-800-222-1222) right away.

#### **Directions**

Single Daily Dosage (per 24 hours)

**children 2 to under 6 years:** one suppository per day or as directed by a doctor

**children under 2 years:** consult a doctor

#### Administering the laxative:

CAUTION: REMOVE ORANGE PROTECTIVE SHIELD BEFORE INSERTING. Hold unit upright, grasping bulb of unit with fingers. Grasp orange protective shield with other hand, pull gently to remove. With steady pressure, gently insert tip into rectum with a slight side-to-side movement, with tip

pointing toward navel. **Discontinue use if resistance is encountered. Forcing the tip can result in injury.** Insertion may be easier if child receiving suppository bears down as if having a bowel movement. This helps relax the muscles around the anus. Squeeze the bulb until nearly all liquid is expelled. While continuing to squeeze the bulb, remove tip from rectum and discard unit. It is not necessary to empty unit completely. The unit contains more than the amount of liquid needed for effective use. A small amount of liquid will remain in the unit after squeezing.

**Left-side position:** Place child on left side with knees bent and arms resting comfortably.

**Knee-chest position:** Have child kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.

## 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

#### PRINCIPAL DISPLAY PANEL

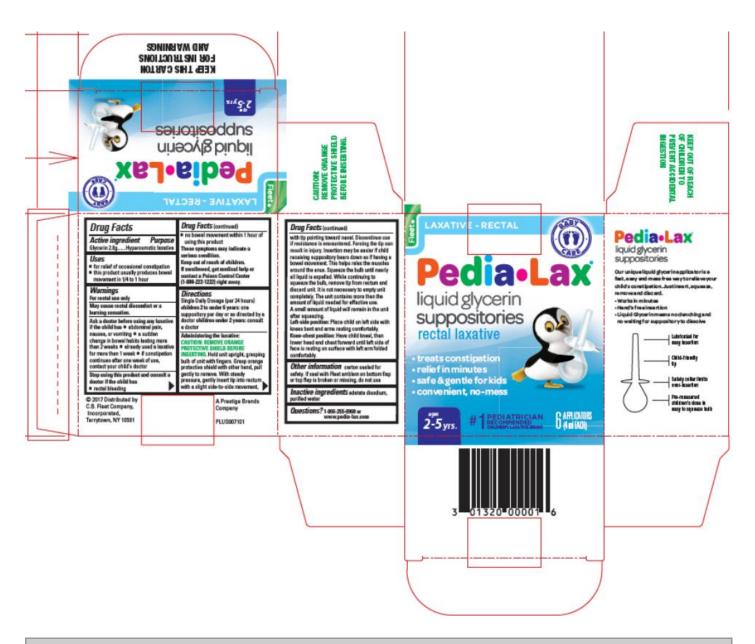
**Baby Care** 

Pedia-Lax®

Liquid glycerin suppositories

rectal laxative

6 applicators (4 ml each)



## **PEDIA-LAX**

glycerin liquid

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:0132-0195

**Route of Administration** RECTAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII: PDC6A3C0OX)	GLYCERIN	2.8 g in 4 mL

Inactive Ingredients			
Ingredient Name	Strength		
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
WATER (UNIL 070 070 VOOR)			

WATER (UNII: 059QF0KO0R)

Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:0132-0195-12	6 in 1 CARTON	02/01/2019		
1		4 mL in 1 APPLICATOR; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part334	0 2/0 1/20 19			

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

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