PEDIATRIC GLYCERIN - glycerin suppository
Cosette Pharmaceuticals, 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.

Pediatric Glycerin Suppositories

ACTIVE INGREDIENT (in each suppository)

Glycerin, USP 1.2 grams

PURPOSE

Laxative

USES

• relieves occasional constipation (irregularity)
• generally produces bowel movement in 1⁄4 to 1 hour

WARNINGS

For rectal use only
Do not use laxative products for longer than 1 week unless directed by a doctor

Ask a doctor before use if your child has
• stomach pain
• nausea
• vomiting
• a sudden change in bowel habits that lasts over 2 weeks

When using this product your child may have rectal discomfort or a burning sensation

Stop use and ask a doctor if your child has rectal bleeding or fails to have a bowel movement after use of a laxative. These could be signs of a serious condition.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

children 2 to under 6 years of age	Insert 1 suppository well into the rectum and retain for 15 minutes; it need not melt to produce laxative action. Do not exceed 1 suppository daily or as directed by a doctor.
children under 2	ask a doctor

OTHER INFORMATION

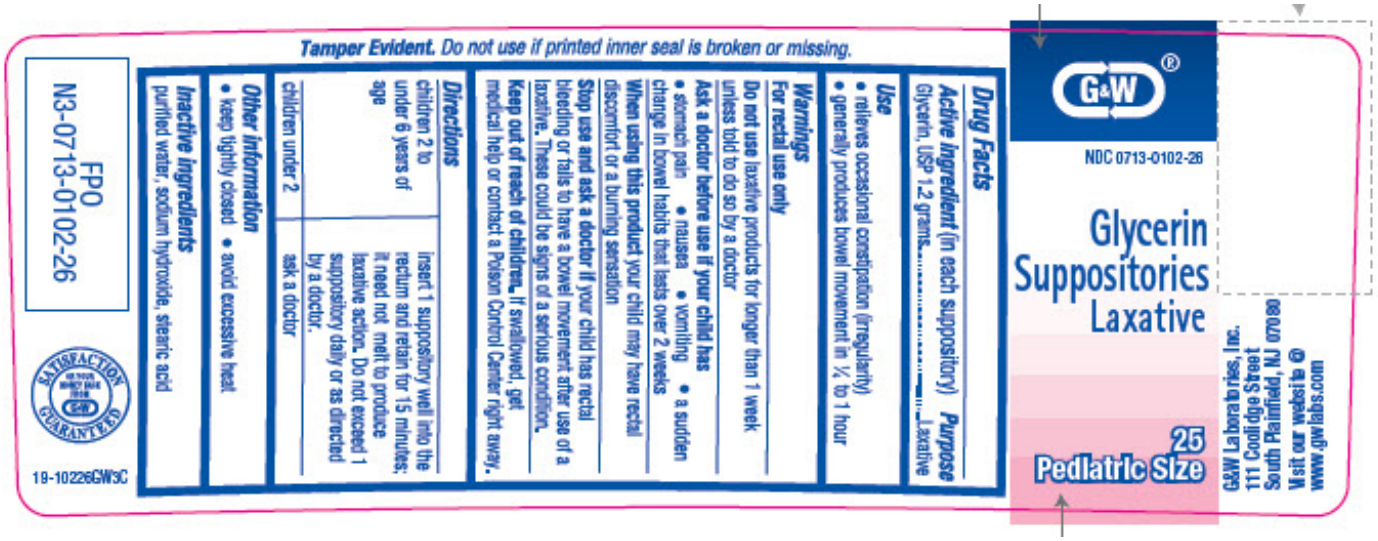
• keep tightly closed
• avoid excessive heat

INACTIVE INGREDIENT

purified water, sodium hydroxide, stearic acid

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

G&W®
NDC 0713-0102-26
Glycerin Suppositories Laxative
25 Pediatric Size
G&W Laboratories, Inc
111 Coolidge Street
South Plainfield, NJ 07080
Visit our website @ www.gwlabs.com



PEDIATRIC GLYCERIN

glycerin suppository

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0713-0102
Route of Administration	RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	1.2 g

Inactive Ingredients	
Ingredient Name	**Strength**
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0102-26	25 in 1 JAR; Type 0: Not a Combination Product	06/08/1987	
2	NDC:0713-0102-13	12 in 1 JAR; Type 0: Not a Combination Product	06/08/1987	
3	NDC:0713-0102-09	10 in 1 CARTON; Type 0: Not a Combination Product	06/08/1987	
4	NDC:0713-0102-25	25 in 1 CARTON; Type 0: Not a Combination Product	06/08/1987	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/08/1987	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0102) , manufacture(0713-0102) , label(0713-0102) , pack(0713-0102)

Revised: 8/2019 Cosette Pharmaceuticals, Inc.