

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.

Adult Glycerin

ACTIVE INGREDIENT (in each suppository)

Glycerin, USP 2.1 grams

PURPOSE

Laxative

USE

- 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 you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

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

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

IF PREGNANT OR BREAST FEEDING

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

adults and children 6 years and over	1 suppository per day or as directed by a doctor
children 2 to under 6 years	use pediatric glycerin suppositories

children under 2 years	ask a doctor
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- insert 1 suppository well up into rectum and retain for 15 minutes
- it need not melt to produce laxative action

OTHER INFORMATION

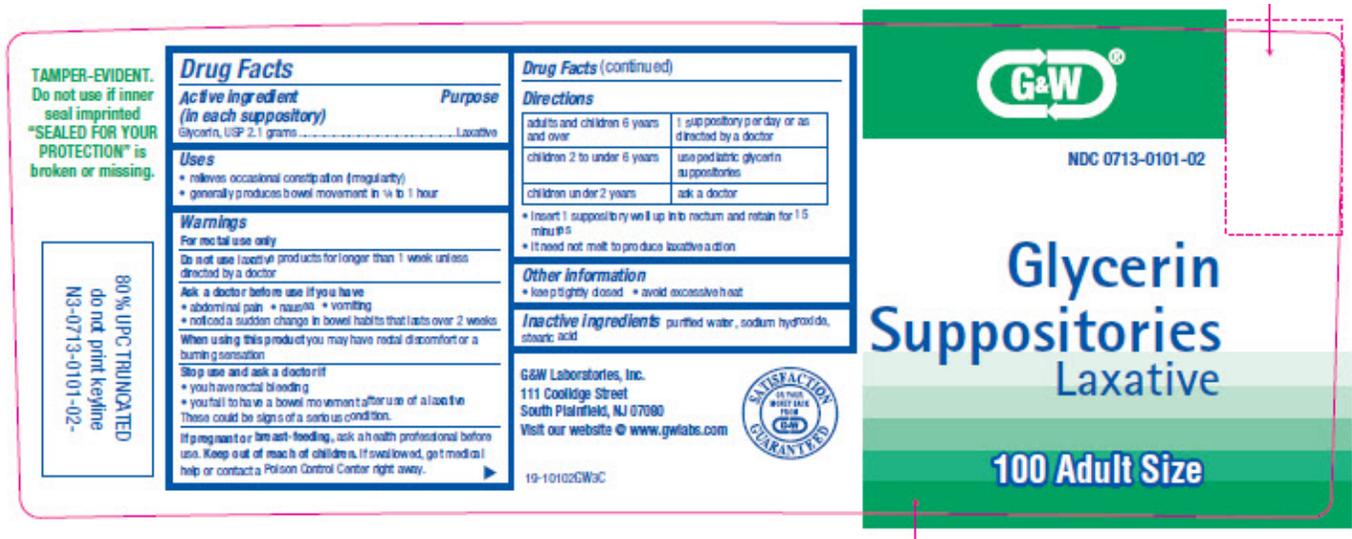
- keep tightly closed
- avoid excessive heat

INACTIVE INGREDIENT

purified water, sodium hydroxide, stearic acid

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0713-0101-02
 Glycerin Suppositories
 Laxative
 100 Adult Size



GLYCERIN

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0713-0101
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2.1 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0101-02	100 in 1 JAR; Type 0: Not a Combination Product	06/08/1987	
2	NDC:0713-0101-13	12 in 1 JAR; Type 0: Not a Combination Product	06/08/1987	
3	NDC:0713-0101-25	25 in 1 CARTON; Type 0: Not a Combination Product	06/08/1987	
4	NDC:0713-0101-26	25 in 1 JAR; Type 0: Not a Combination Product	06/08/1987	
5	NDC:0713-0101-51	51 in 1 JAR; Type 0: Not a Combination Product	06/08/1987	
6	NDC:0713-0101-09	10 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	MANUFACTURE(0713-0101)

Revised: 8/2019

Cosette Pharmaceuticals, Inc.