

GLYCERIN CHILDREN- glycerin suppository
Rising Pharma Holdings, 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.

Children's Glycerin Suppositories 1.2 g

Drug Facts

Active ingredient (in each suppository)

Glycerin USP, 1.2 grams

Purpose

Laxative

Uses

- for relief of occasional constipation
- this product usually produces bowel movement in 1/4 to 1 hour

Warnings

For rectal use only

Do not use for longer than one week unless directed by a doctor

Ask a doctor before use if the child has

- stomach pain, nausea or vomiting
- a sudden change in bowel habits lasting more than 2 weeks

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

Stop use and ask a doctor if child has

- rectal bleeding
- no bowel movement after using this product

These 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

- children 2 to under 6 years of age : 1 suppository once daily
- children under 2 years : ask a doctor
- insert 1 suppository well up into the rectum and retain for 15 minutes
- it need not melt to produce laxative action

Other information

keep away from excessive heat.

Inactive ingredients purified water, sodium stearate

Questions or Comments? Call **1-844-474-7464**

TAMPER EVIDENT: DO NOT USE IF SEALED WRAPPER AROUND SUPPOSITORIES IS BROKEN OR MISSING

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Made in India

CODE NO.: MH/DRUGS/25-KD/724

Issued: 08/2023

NDC 57237-326-52 (5 blisters of 5 suppositories)

Children's Glycerin Suppositories 1.2 g

LAXATIVE

For fast, gentle relief of occasional constipation

For ages 2 to 5 years

SR. No.: XXXXXXXXXXXXXXXXXXXX
LOT: XXXXXXXX
EXP: YYYY/MM



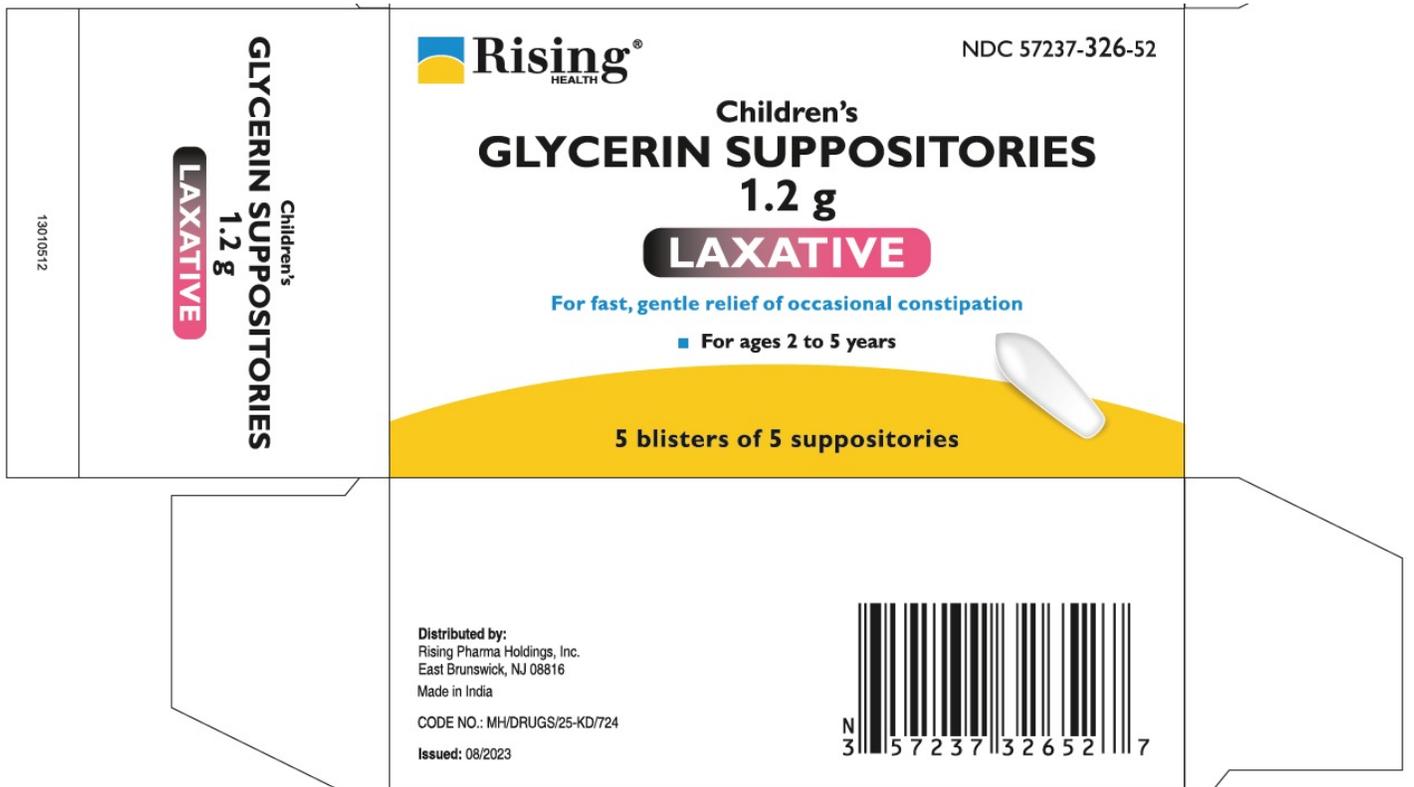
SNK

Drug Facts Active ingredient (in each suppository) Purpose Glycerin USP, 1.2 grams Laxative	Drug Facts (continued) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
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Children's
GLYCERIN SUPPOSITORIES
1.2 g
LAXATIVE

TAMPER EVIDENT: DO NOT
USE IF SEALED WRAPPER
AROUND SUPPOSITORIES IS
BROKEN OR MISSING



NDC 57237-326-51 (5 suppositories in 1 blister pack)

Front Foil



Children's
**GLYCERIN
SUPPOSITORIES 1.2 g**
For rectal use only



NDC 57237-326-51



Children's
**GLYCERIN
SUPPOSITORIES 1.2 g**
For rectal use only



NDC 57237-326-51

Code No.:
MH/DRUGS/25-KD/724



Children's
**GLYCERIN
SUPPOSITORIES 1.2 g**
For rectal use only



NDC 57237-326-51

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12004709

Back Foil

~~Dist. By: Rising Pharma Holdings, Inc.~~
Keep away from excessive heat.

~~Dist. By: Rising Pharma Holdings, Inc.~~
Keep away from excessive heat.

~~Dist. By: Rising Pharma Holdings, Inc.~~
Keep away from excessive heat.

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12004705

GLYCERIN CHILDREN

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-326
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
WATER (UNII: 059QF0KO0R)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	

Product Characteristics

Color	white (clear)	Score	
Shape	BULLET	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-326-21	2 in 1 CARTON	08/24/2023	
1	NDC:57237-326-16	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57237-326-52	5 in 1 CARTON	08/24/2023	
2	NDC:57237-326-51	5 in 1 BLISTER PACK; 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	08/24/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Establishment

Name	Address	ID/FEI	Business Operations
Bliss GVS Pharma Limited		675630493	manufacture(57237-326) , analysis(57237-326) , pack(57237-326)

Revised: 9/2023

Rising Pharma Holdings, Inc.