BLISS GVS CHILDREN- glycerin suppository Bliss GVS Pharma Limited

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.

Bliss Glycerin Suppositories, Children

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

IFor 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

- abdominal 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 the 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 suppository well up into 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 1-888-830-6075

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

Manufactured and Marketed by:

BLISS GVS PHARMA LTD.

102, Hyde Park, Saki Vihar Road, Andheri (E)

Mumbai-400 072, INDIA

Email: info@blissgvs.com • www.blissgvs.com

NDC 72701-105-12

Children GLYCERIN SUPPOSITORIES

LAXATIVE

For ages 2 to 5 years

For fast, gentle relief of occasional constipation

12 Suppositories

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Drug Facts (continued)

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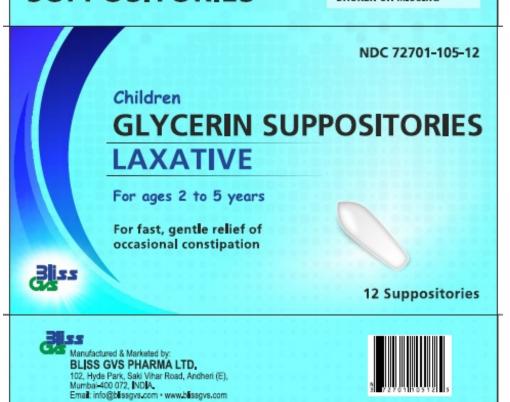
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GLYCERIN SUPPOSITORIES

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BLISS GVS CHILDREN

glycerin suppository

Product Information HUMAN OTC DRUG Item Code (Source) NDC:72701-105 Product Type **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)	

1	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:72701-105-12	2 in 1 CARTON	01/20/2020			
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:72701-105-25	5 in 1 CARTON	01/20/2020			
2		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	01/20/2020	

Labeler - Bliss GVS Pharma Limited (675629890)

Establishment			
Name	Address	ID/FEI	Business Operations
Bliss GVS Pharma Limited		675630493	manufacture(72701-105), analysis(72701-105), pack(72701-105), label(72701-105)

Revised: 1/2020 Bliss GVS Pharma Limited