GLYCERIN - glycerin suppository ATLANTIC BIOLOGICALS CORP.

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.

GNP Glycerin Supp.

Active ingredient (in each suppository)

Glycerin 2.1 g

Purpose

Laxative

Uses

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

Warnings

For rectal use only

May cause rectal discomfort of burning sensation

Ask a Doctor before using any laxative if you have

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits lasting more than two weeks
- already used a laxative for more than 1 week

Stop use and consult a doctor if you have

- rectal bleeding
- no bowel movement after 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 right away.

Directions

Single daily dosage

adults and children 6 years and over 1 suppository, or as directed by a doctor

children 2 to under 6 years use Child Suppositories

Insert suppository well up into rectum.

Suppository need not melt completely to produce laxative action.

Other information

- Store container tightly closed.
- Keep away from excessive heat.

Inactive ingredients

purified water, sodium hydroxide, stearic acid

Glycerin Suppositories

The product package shown represents a sample of that currently in use. Additional packaging may also be available.

Glycerin Suppositories, 30 & 60 ct per case

Distributed by:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

NDC 17856-0221-01 Glycerin Suppositories

2 Gram Adult Laxative

UNIT DOSE

Compare to Fleet® Glycerin Suppositories

PACKAGING INFORMATION:

Dosage per Suppositories: 2 Grams Suppositories per Case: 60

See Package Insert for Drug Facts

Other Information:

Store at room temperature away from moisture and heat.

KEEP GYLCERINE SUPPOSITORIES AND ALL MEDICINES OUT OF THE REACH OF CHILDREN

Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp. 20101 N.E. 16th Place Miami, FL 33179

*Retain box label and package insert for drug information.

Questions or Comments: Call 1-800-509-7592

UDS-Lot No: XXXXXX MFG Lot No: XXXXXXXX Exp Date: XX/XX/XXXX



NDC 17856-0221-02

Glycerin Suppositories

2 Gram Adult Laxative

UNIT DOSE

Compare to Fleet® Glycerin Suppositories

PACKAGING INFORMATION:

Dosage per Suppositories: 2 Grams Suppositories per Case: 30

See Package Insert for Drug Facts

Other Information:

Store at room temperature away from moisture and heat.

KEEP GYLCERINE SUPPOSITORIES AND ALL MEDICINES

OUT OF THE REACH OF CHILDREN

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UDS-Lot No: XXXXXXX
MFG Lot No: XXXXXXXX
Exp Date: XX/XX/XXXX



glycerin suppository

GLYCERIN

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:17856-0221(NDC:46122-221)

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 HYDRO XIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0221-2	30 in 1 BOX, UNIT-DOSE	12/19/2018	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:17856-0221-1	60 in 1 BOX, UNIT-DOSE	12/19/2018	
2		1 in 1 POUCH; 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	12/19/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0221), relabel(17856-0221)

Revised: 12/2018 ATLANTIC BIOLOGICALS CORP.