## 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.

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### GNP Pediatric Glycerin Supp.

## Active ingredient (in each suppository)

Glycerin 1.2 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 child has

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

## Stop use and consult a doctor if child has

- 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			
Children 2 to under 6 years	1 suppository, or as directed by a doctor		
children under 2 years	ask a doctor		
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

### **Pediatriic Glycerin Suppositories**

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

Pediatric Glycerin Suppositories 30 & 60 per cases.

### Distributed by:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

## NDC 17856-0222-01

# **Glycerin Suppositories**

# 1.2 Gram Pediatric Laxative

#### UNIT DOSE

Compare to Fleet® Glycerin Suppositories

#### PACKAGING INFORMATION:

Dosage per Suppositories: 1.2 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 17856-0222-02 Glycerin Suppositories

## 1.2 Gram Pediatric Laxative

#### UNIT DOSE

Compare to Fleet® Glycerin Suppositories

#### PACKAGING INFORMATION:

Dosage per Suppositories: 1.2 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

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

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



GLYCERIN							
glycerin suppository							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0222(NDC:4	46 122-222)			
Route of Administration	RECTAL						
Active Ingredient/Active Moiety							
Ingredient Name			<b>Basis of Strength</b>	Strength			
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)			GLYCERIN	1.2 g			
Inactive Ingredients							

Ingredient Name					Strength		
WATER (UNII: 059QF0KO0R)							
so	DIUM HYDRO XIDE	(UNII: 55X04QC32I)					
ST	EARIC ACID (UNII: 4	ELV7Z65AP)					
Packaging							
#	Item Code	Package Description	Ν	farketing Start Date	Marketing End Date		
1	NDC:17856-0222-2	30 in 1 BOX, UNIT-DOSE	12/	/19/2018			
1		1 in 1 POUCH; Type 0: Not a Combination Product					
2	NDC:17856-0222-1	60 in 1 BOX, UNIT-DOSE	12/	/19/2018			
2		1 in 1 POUCH; Type 0: Not a Combination Product					
ъ.	arketing Info	rmation					
IVI			Application Number or Monograph Citation				
	Marketing Categor	y Application Number or Monograph Citat	ion	Marketing Start Date	Marketing End Date		

# Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

## Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0222), repack(17856-0222)

Revised: 12/2018

ATLANTIC BIOLOGICALS CORP.