

**AVEDANA GLYCERIN LAXATIVE- glycerin suppository suppository
Unipack, 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.

Active Ingredient

Active Ingredient (in each suppository)	Purpose
Glycerin, USP 2 grams	Laxative

Uses

Uses - relieves occasional constipation (irregularity)

- generally produces bowel movement in 1/4 to 1 hour

Warnings

For rectal use only

Do not use

Do not use laxative products for longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

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

When using this product

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

Stop use and ask a doctor if

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,

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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
15 minutes; it need not melt to

Insert 1 suppository well into the rectum and retain for

produce laxative action. Do not exceed 1 suppository

daily or as directed by a doctor

children 2 to under 6 years

use Child Suppositories

children under 2 years

ask a doctor

insert 1 suppository well up into the rectum and retain fo 15 minutes

it need not melt to produce laxative action

Other information

- keep tightly closed - avoid excessive heat

Inactive ingredients

purified water, sodium hydroxide, stearic acid

Product Label

1.75" height

Avedana
...means "no pain"

Compare to active ingredient
In Fleet® Glycerin Suppositories*

GLYCERIN SUPPOSITORIES LAXATIVE

For fast, gentle relief of occasional constipation
25 ADULT SIZE

NDC 43719-440-25

Important Information: Do not use if perforated, broken seal is broken or missing.

6.125" width

Orange is die line and does not print!

Drug Facts

Active ingredient (in each suppository) Purpose
Glycerin, USP 2 grams Laxative

Uses • relieves occasional constipation (irregularity)
• generally produces bowel movement in ¼ 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

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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 of age and over	Insert 1 suppository well into the rectum and retain for 15 minutes; it need not melt to produce laxative action. Do not exceed 1 suppository daily or as directed by a doctor
children 2 to under 6 years	use Child Suppositories
children under 2 years	ask a doctor

Other information
• keep tightly closed • avoid excessive heat

Inactive ingredients
purified water, sodium hydroxide, stearic acid

*This product is not manufactured or distributed by C.B. Fleet Co., Inc., owner of the registered trademark Fleet®.

Manufactured by:
Unipack, Inc.
Made in the U.S.A.



glycerin suppository suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-440
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	83 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	8.5 g in 100 g
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	1.2 g in 100 g
WATER (UNII: 059QF0K00R)	7.3 g in 100 g

Product Characteristics

Color	white (CLEAR)	Score	
Shape	BULLET	Size	32mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-440-25	62.5 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/18/2014	

Labeler - Unipack, Inc. (009248480)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(43749-440)