

AVEDANA GLYCERIN LAXATIVE- glycerin 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.

Avedana® Glycerin Suppositories 100 count

Drug Facts

Active Ingredient

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

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

Ask a doctor before use if you have

- abdominal 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
- you 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.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 6 years and over
children 2 to under 6 years
children under 2 years

1 suppository per day or as directed by a doctor
use Child Suppositories
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 tightly closed - avoid excessive heat

Inactive ingredients

purified water, sodium hydroxide, stearic acid

Product Label

Avedana® Glycerin Suppositories | 100 count in a Jar |

Avedana
...means no pain!

Compare to active ingredient in Fleet® Glycerin Suppositories*

GLYCERIN SUPPOSITORIES

LAXATIVE

For fast, gentle relief of occasional constipation

100 ADULT SUPPOSITORIES

Drug Facts	
Active ingredient (in each suppository) Glycerin, USP 2 grams	Purpose Laxative
Uses <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• abdominal 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. Stop use and ask a doctor if <ul style="list-style-type: none">• you have rectal bleeding• you fail to have a bowel movement after use of a laxative These could be signs of a serious condition. 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.	

Drug Facts (continued)	
Directions	
adults and children 6 years and over	1 suppository per day or as directed by a doctor
children 2 to under 6 years	use CVS/pharmacy™ Child Suppositories
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 tightly closed • avoid excessive heat	
Inactive ingredients purified water, sodium hydroxide, stearic acid	
*This Avedana™ product is not manufactured or distributed by C.B.Fleet Co., Inc., owner of the registered trademark Fleet®.	
TAMPER EVIDENT. Do not use if inner seal imprinted "SEALED FOR YOUR PROTECTION" is broken or missing.	

Manufactured By:
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(724)783-7381
Made in USA

NDC 43749 440 00

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AVEDANA GLYCERIN LAXATIVE

glycerin 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	2 g

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

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:43749-440-00	100 in 1 JAR; Type 0: Not a Combination Product	09/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/17/2017	

Labeler - Unipack, Inc. (009248480)

Establishment

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

Revised: 1/2021

Unipack, Inc.