

CVS ADULT ENEMA- docusate sodium w/benzocaine liquid
Summit Pharmaceuticals

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.

CVS Adult Mini-Enema

Drug Facts

Active Ingredients (in each delivered dose)

Benzocaine 20 mg

Docusate Sodium USP 283 mg

Purpose

Benzocaine 20mg.....Anesthetic

Docusate Sodium USP 283 mg.....Stool Softener Laxative

Uses

- For the relief of occasional constipation (irregularity).
- This product generally produces a bowel movement in 2 to 15 minutes.

Warnings

For rectal use only

Do not use

- If individual is sensitive to Benzocaine.
- If you are presently taking mineral oil, unless directed by a doctor.
- When abdomen pain, nausea or vomiting are present.
- For a period longer than 1 week unless directed by a doctor.

Stop use and ask a doctor if

- Symptoms last more than 2 weeks.
- You have rectal bleeding or fail to have a bowel movement after use. This may indicate a serious condition.

Pregnant or lactating women, ask a health professional before use.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 12 years and older (with adult supervision), one to three units daily. Children under 12 years of age, consult a doctor prior to use.

- Twist off and remove tip.
- Lubricate tip prior to insertion: Place a few drops of the tube's liquid content on the shaft prior to insertion. Also apply liquid content or lubricant to the anus before inserting the mini-enema.
- Positioning: For best results, lay on left side with knees bent. Alternate Positions: Administer while seated on the toilet. Or, kneel, then lower head and chest forward until side of face is resting on the surface.
- With steady pressure, gently insert the tube into the rectum with care to prevent damage to the rectal wall. Insert up to the shoulder of tube. Squeeze to empty the contents. Keep the tube squeezed until it is removed from the rectum. After the contents have been emptied, remove the disposable tube and discard. A small amount of liquid may remain in the unit after use.

Other Information

Store at room temperature 15° - 30° C (59° - 86° F)

Inactive Ingredients

Glycerine USP and Polyethylene Glycol

Distributed by:

CVS Pharmacy, Inc.

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Woonsocket, RI 02895

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V-31560



CVS ADULT ENEMA

docusate sodium w/benzocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17433-9991
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	283 mg in 4.6 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 mg in 4.6 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17433-9991-5	5 in 1 BOX	09/01/2014	06/30/2024
1	NDC:17433-9991-1	4.6 g in 1 TUBE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/01/2014	06/30/2024

Labeler - Summit Pharmaceuticals (010717819)

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