DOCUSATE SODIUM- docusate sodium capsule, liquid filled
Safecor Health, LLC

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.

Docusate Sodium, USP
Stool Softener

Active ingredient (in each softgel)

Docusate Sodium 250 mg

Purpose

Stool Softener

Keep Out of Reach of Children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

- For the relief of occasional constipation.
- Helps to prevent dry, hard stools.
- This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use:

- If you are currently taking mineral oil, unless directed by a doctor.
- When abdominal pain, nausea, or vomiting are present.
- For longer than one week unless directed by a doctor.

Ask a doctor before use

if you notice a sudden change in bowel habits that persists over a period of two weeks.

Stop use and ask a doctor

if you have rectal bleeding or you fail to have a bowel movement after use.

If you are pregnant or breast-feeding,

ask a healthcare professional before use.

Directions

Adults and Children over 12 years of age	Take orally 1 softgel preferably at bedtime for 2-3 days or until bowel movements are normal, or as directed by a doctor.
Children under 12 years of age	Do not use this product for children under 12 years of age, unless directed by a doctor.

Other Information

- **Each softgel contains 13 mg of Sodium.**
- Keep lid tightly closed.
- Store at room temperature between 15°C to 30°C (59°F to 86°F).
- Do not use if printed seal under cap is broken or missing.
- For identification purposes, each softgel will have an imprint that reads NV12.

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, Gelatin, Glycerin, Ink (Edible), Polyethylene Glycol, Propylene Glycol, Purified Water, Sorbitol

Questions

Call 1 (800) 447-1006

Package/Label Principal Display Panel

Safecor Health

Docusate Sodium, USP
250 mg Each

NDC 48433-101-01

100 Unit Dose Softgels

Packaged and Distributed by:

Safecor Health, LLC

Columbus, OH 43204

SAFECOR HEALTH

DOCUSATE SODIUM

250 mg

NDC 48433-101-01

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Drug Facts

This package is not child resistant. For institutional use only.

Active Ingredients *(in each softgel)* — **Purpose**

Docusate Sodium 250mg ..... Stool Softener

Uses: • For the relief of occasional constipation. • Helps to prevent dry, hard stools.• This product generally produces a bowel movement within 12 to 72 hours.

WARNINGS Do Not Use: • If you are currently taking mineral oil, unless directed by a doctor. • When abdominal pain, nausea or vomiting are present.• For longer than 1 week unless directed by a doctor.

Ask a doctor before use if you notice a sudden change in bowel habits that persists over a period of two weeks. **Stop use and ask a doctor** if you have rectal bleeding or you fail to have a bowel movement after using this product. **If pregnant or breast-feeding,** ask a health care professional before use.

Keep this and all drugs out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions: Adults and Children ≥12 years old	Take orally 1 softgel preferably at bedtime for 2 to 3 days or until bowel movements are normal, or as directed by a doctor.
Children <12 years old	Do not use this product for children <12 years old, unless directed by a doctor.

Other Information: • **Each softgel contains 13 mg of Sodium.** • Store at room temperature between 15° to 30°C (59° to 86°F). • Do not use if blister pack seals are broken • For identification purposes, each softgel will have an imprint that reads NV12.

Inactive Ingredients: FD & C Red #40, FD & C Yellow #6, Gelatin, Glycerin, Ink (Edible). Polyethylene Glycol, Propylene Glycol, Purified Water, Sorbitol.

Distributed by: Safecor Health, LLC
317 New Boston Street, Woburn, MA 01801 USA

101-00
Rev. 10/2013

SAFECOR HEALTH

DOCUSATE SODIUM

250 mg

NDC 48433-101-01

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100 UNIT DOSE SOFTGELS

Questions or Comments? Call 800-447-1006

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:48433-101(NDC:54629-601)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	RED	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	NV12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-101-01	100 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	05/01/2000	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/01/2000	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		078805287	REPACK(48433-101)

Revised: 1/2022

Safecor Health, LLC