TOPCARE STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
TOPCO ASSOCIATES LLC

DOCUSATE SODIUM 250 mg Two-Tone, Capsule, liquid filled

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 250 mg

Purpose

Stool softener

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 12 to 72 hours

Warnings

Do not use

- if you are presently taking mineral oil, unless told to do so by a doctor

Ask a doctor before use if you have

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

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.
- you need to use a stool softener laxative for more than 1 week

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

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

Directions

Take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

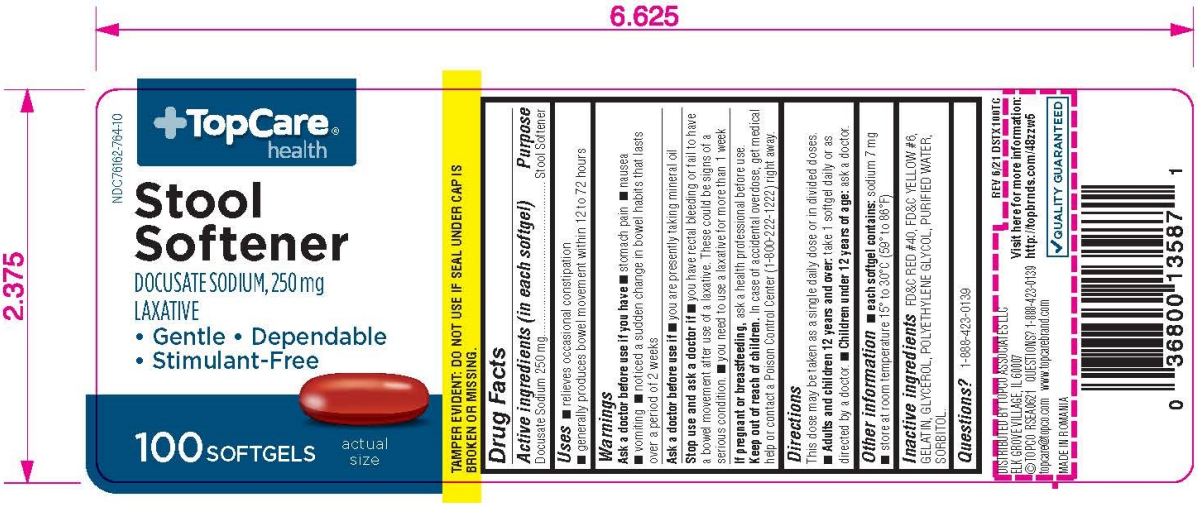
Other information

- each softgel contains: **sodium 5 mg**
- **VERY LOW SODIUM**
- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive Ingredients

D&C Red No. 33, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerol, Polyethylene glycol, purified water, sorbitol, titanium dioxide

Display Panel



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ELK GROVE VILLAGE, IL 60007
©TOPCO RSEA0621 QUESTIONS? 1-888-423-0139 topcare@topco.com
www.topcarebrand.com

TOPCARE STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76162-764
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red, white (Two-Tone)	**Score**	no score
Shape	CAPSULE (OVAL)	**Size**	20mm
Flavor		**Imprint Code**	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-764-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M007	07/20/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Reese Pharmaceutical (004172052)

Revised: 12/2024 TOPCO ASSOCIATES LLC