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

Docusate Sodium 100 mg..... Stool Softener

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 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 7 mg
- store at room temperature 15° to 30°C (59° to 86°F)

Inactive Ingredients

FD&C RED NO. 40, FD&C YELLOW NO. 6, GELATIN BOVINE, GLYCEROL, POLYETHYLENE GLYCOL, PURIFIED WATER, SORBITOL.

Display Panel



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TOPCARE STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-761	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg	

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
GLYCERIN (UNII: PDC6A3C0OX)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	red	Score	no score
Shape	CAPSULE (OVAL)	Size	12mm
Flavor		Imprint Code	SCU1
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76162-761- 25	1 in 1 CARTON	07/20/2021		
1		25 in 1 BOTTLE; Type 0: Not a Combination Product			

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