

DOCUSATE SODIUM- docusate sodium capsule, liquid filled
Spirit Pharmaceuticals 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.

VALUMEDS STOOL SOFTENER

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool Softner laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are presently taking mineral oil

Stop use and ask a doctor if you

- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.
- you need to use 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.1(800)222-1222

Directions

take with a glass of water

Adults and children 12 years and over	1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses
Children 2 to under 12 years of age	1 softgel daily.
Children under 2 years of age	Ask a doctor

Other information

- Store at room temperature 20-25°C (68-77°F)
- protect from excessive humidity
- do not use this product if the safety seal under the cap is torn or missing

Inactive ingredients

FD&C Red#40, FD&C Yellow#6, gelatin, glycerin, polyethylene glycol 400, propylene glycol, purified water, sorbitol solution, titanium dioxide.

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL- Valumed's Stool Softener 30 softgels Bottle Labels-Single Tone

VALUMEDS™

Compare to the active ingredient in

Dulcolax® Stool Softener*

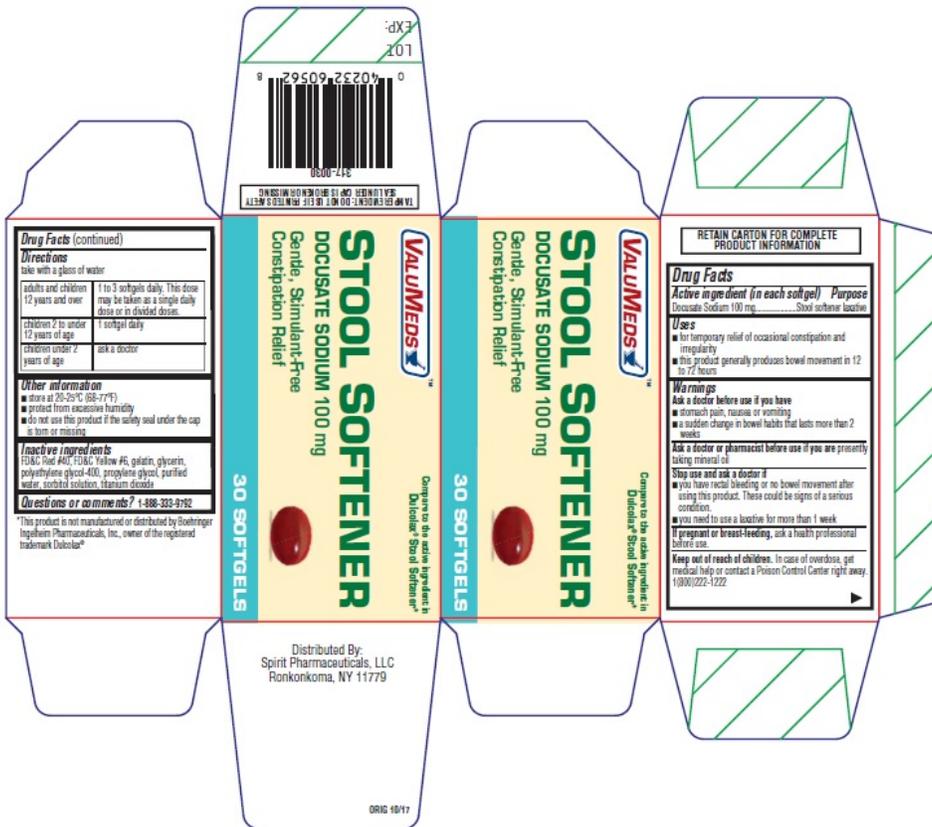
STOOL SOFTENER

DOCUSATE SODIUM 100 mg

Gentle, Stimulant-Free Relief

Constipation Relief

30 SOFTGELS



DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0317
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	125
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0317-3	1 in 1 CARTON	04/10/2018	
1		30 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 not final	part334	04/10/2018	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(68210-0317)