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

VALUMEDS STOOL SOFTENER

Drug Facts

Active ingredient (in each gelcaps)

Docusate Sodium 100 mg

Purpose

Stool Softner

Uses

- for the prevention of the dry, hard stools
- for relief of occassional constipation. This product generally produces a bowel movement within 12 to 72 hours

Do not use

if you are currently taking mineral oil, unless directed to so 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 2 weeks

Stop use abd ask a doctor if you

have rectal bleeding fail to have a bowel movement occur after use.

If pregnant or breast-feeding

ask a health professional before use

Keep out of reach of children

In case of accidental overdose, get medical help or contact a Poison Control Center 1(800)222-1222 immediately.

Stop use and ask a doctor if you

have rectal bleeding fail to have bowel movement occur after use.

If pregnant or breast feeding

Ask a health professional before use

Keep out of reach of children

In case of accidental overdose, get medical help or contact a Poison Control Center 1-800-222-1222 immediately.

Directions

- adult and children 12 years and over: take 1-3 gelcaps, preferably at bedtime
- children 2 to under 12 years of age: take 1 gelcap at bedtime
- children under 2 years of age: ask a doctor

Other information

- Store at room temperature 15-30°C (59-86°F)
- do not use if safety seal under cap is torn or missing

Inactive ingredients

FD&C Red #33, FD&C Red#40, FD&C Yellow#6, gelatin, glycerin, polyethylene glycol 400, propylene glycol, purified water, shellac, sorbitol solution, titanium dioxide.

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL-

Valumeds Stool Softener 100capgels Bottle Labels

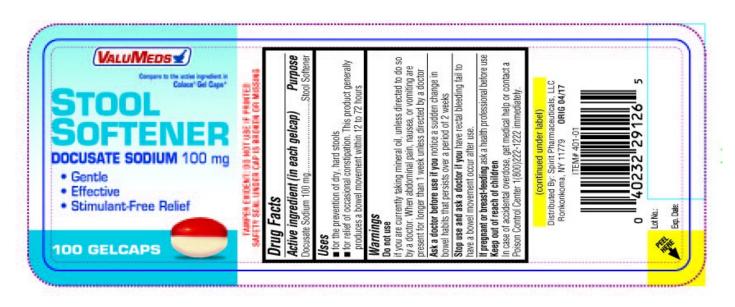
VALUMEDS

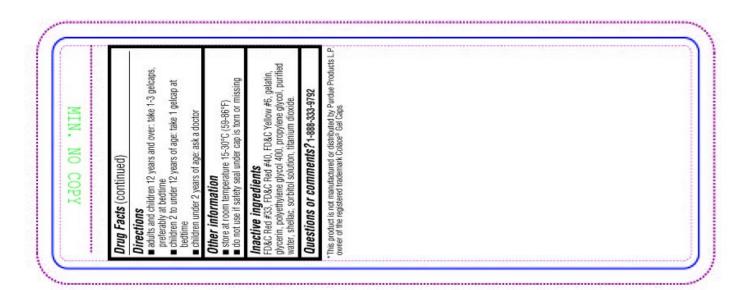
STOOL

SOFTENER

DOCUSATE SODIUM 100 mg

- Gentle
- Effective
- Stimulant-Free Relief





DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0305
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)				
SHELLAC (UNII: 46N107B710)				
WATER (UNII: 059QF0KO0R)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
SORBITOL (UNII: 506T60A25R)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	white, red	Score	no score	
Shape	CAPSULE	Size	12mm	
Flavor		Imprint Code	413	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68210- 0305-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2017		
2	NDC:68210- 0305-3	1 in 1 CARTON	04/11/2018		
2		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 Drug	M007	05/18/2017		

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023 Spirit Pharmaceuticals LLC