

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 100cappels Bottle Labels

VALUMEDS


STOOL

SOFTENER

DOCUSATE SODIUM 100 mg

- Gentle
- Effective
- Stimulant-Free Relief

100 GELCAPS




Compare to the active ingredient in Colace® Gel Caps*

STOOL SOFTENER

DOCUSATE SODIUM 100 mg

- Gentle
- Effective
- Stimulant-Free Relief



100 GELCAPS


TAMPER EVIDENT DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BLENDED OR MISSING

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Warnings	Do not use if you are currently taking mineral oil, unless directed to do 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 and ask a doctor if you have rectal bleeding that 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.			

(continued under label)


Distributed By: Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779 **ORIG 04/17**

ITEM# 401-01



Lot No.: **0 40232 29126 5**

Exp. Date:



100 ON *MIN

Drug Facts (continued)

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*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace® Gel Caps

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: 46N107B71O)	
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			

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