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

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

PRICNIPAL DISPLAY PANEL

Compare to the active ingredient in

Colace ® Gel Caps *

STOOL

SOFTENER

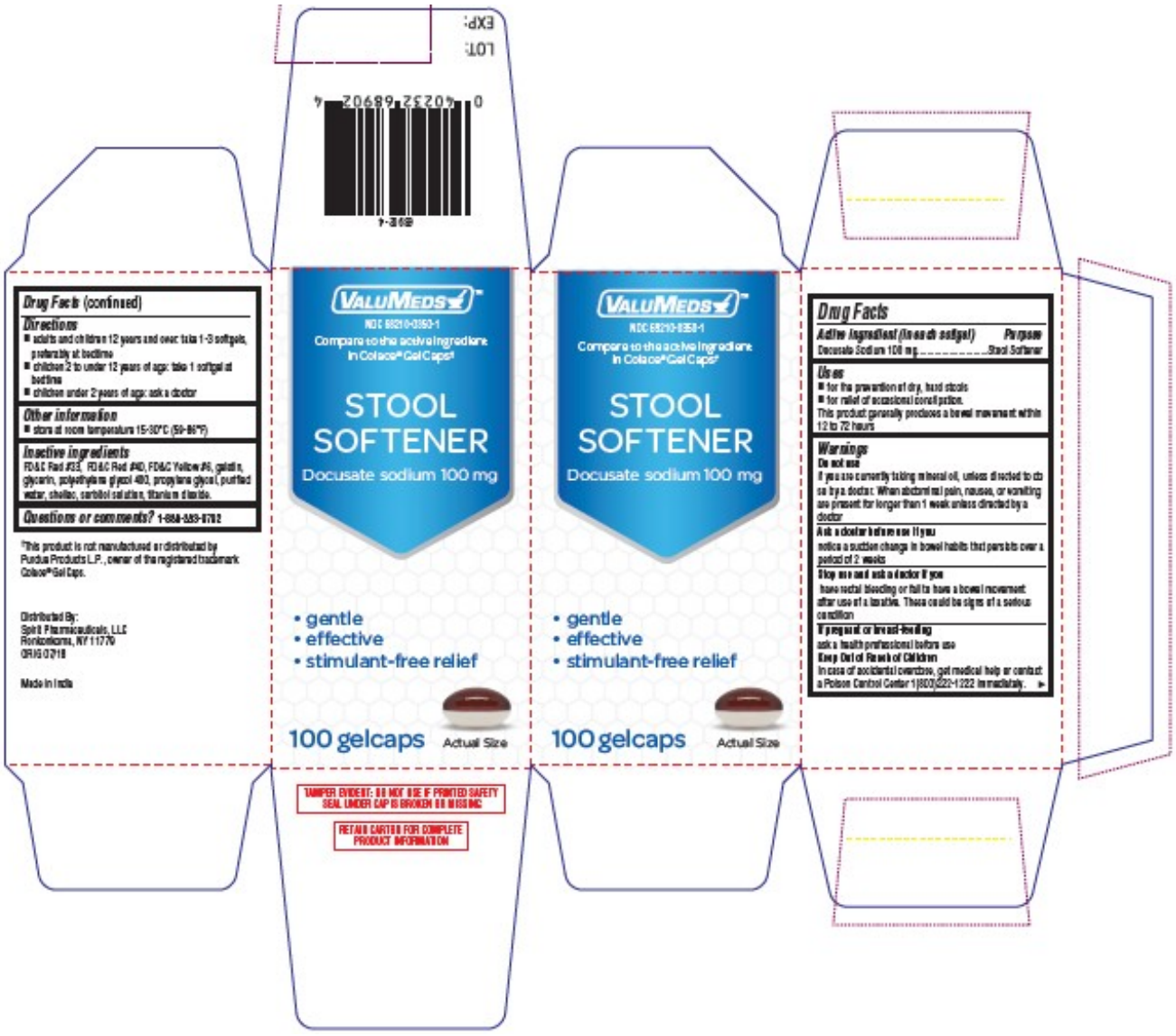
DOCUSATE SODIUM 100 mg

Gentle

Effective

Stimulant-Free Relief

100 GELCAPS



DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0350
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:68210-0350-1	1 in 1 CARTON	03/10/2020	
1		100 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	03/10/2020	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024 Spirit Pharmaceuticals LLC