

**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 occasional 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 and 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 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.

## **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**

### **Compare to the active ingredient in**

Colace ® Gel Caps \*

STOOL

SOFTENER

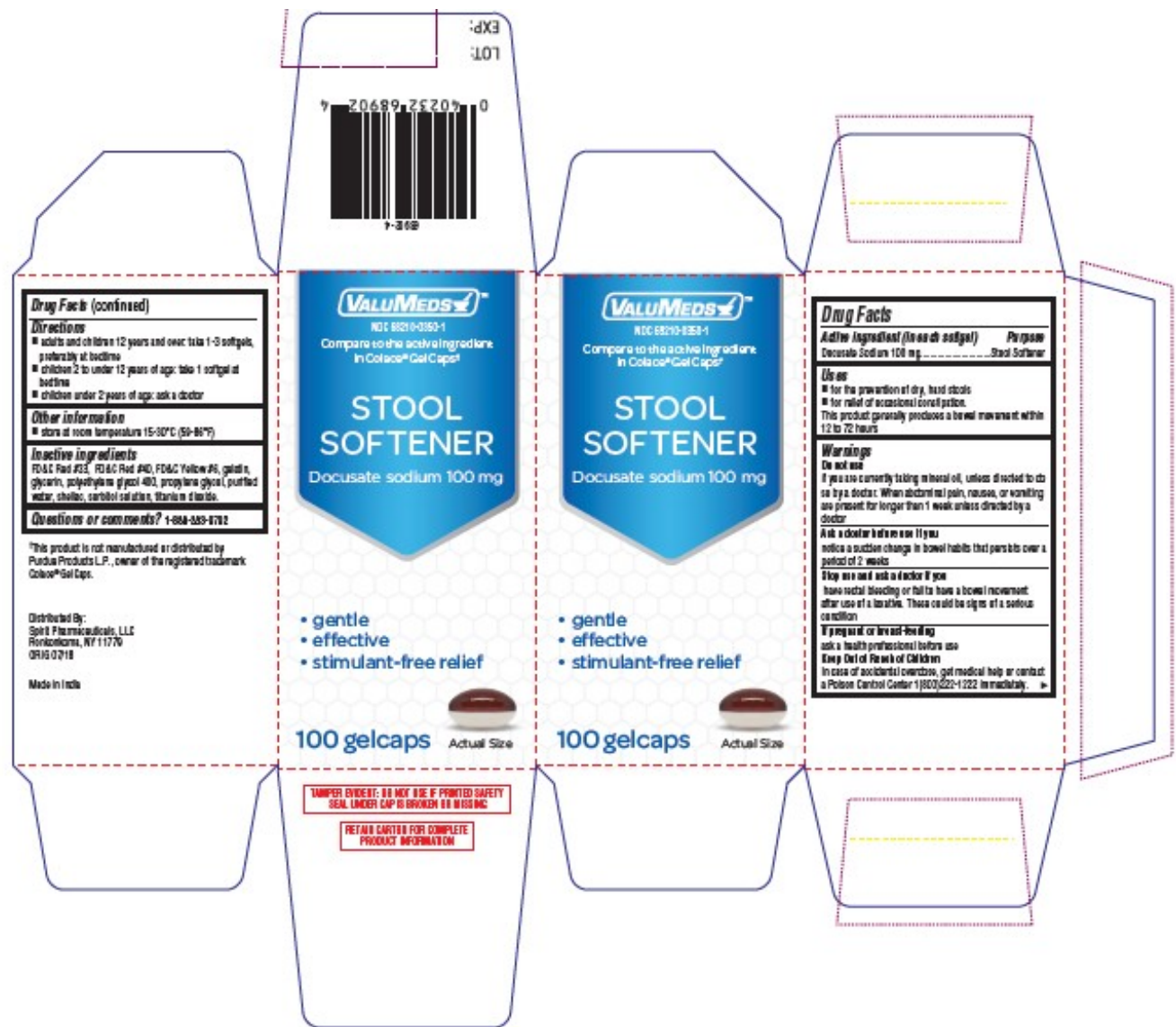
DOCUSATE SODIUM 100 mg

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

<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white, red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	413
<b>Contains</b>			

### 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: 12/2023

Spirit Pharmaceuticals LLC