

**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.*

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**Docusate Sodium capsules USP 100mg**

***Drug Facts***

**Active ingredient (in each capsule)**

Docusate sodium 100 mg

**Purpose**

Stool softener

**Uses**

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

**Warnings**

**Do not use**

- if you are presently taking mineral oil, unless told to do so by a doctor

**Ask a doctor before use if you have**

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a 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.

**Directions**

- Take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1-3 capsules daily
children 2 to under 12 years of	take 1 capsule daily

age	take 1 capsule daily
children under 2 years	ask a doctor

### Inactive ingredients

D&C Red No. 33, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, methylparaben, PEG 400, propylene glycol, propylparaben, sorbitol, titanium dioxide

### PRINCIPAL DISPLAY PANEL

#### Docusate Sodium capsules USP 100mg

Each Softgel Contains:

(Docusate Sodium USP 100mg)

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LOT NO :	QUANTITY:
DRUM NO :	NDC NO : 68210-0401-*
MFG DATE :	EXP DATE :

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#### WARNING:

KEEP OUT OF REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPERATURE OF 59° – 86°F (15° – 30°C)  
PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.  
CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D & C.ACT AND REGULATIONS THEREUNDER.

MANUFACTURED BY:

**SOFTGEL HEALTHCARE PVT LIMITED**

INDIA

LABELLER CODE : 35916

LIC NO. : TN/DRUGS/00002124

MANUFACTURED FOR:

**SPIRIT PHARMACEUTICALS LLC**

225 LINCOLN HWY, STE 205

FAIRLESS HILLS, PA 19030

PH.# 215 943 4000

FAX.# 215 943 4039

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

- 1 - 10
- 2 - 30
- 3 - 100
- 4 - 1000
- 5 - 16000
- 6 - 20000

**Docosate Sodium capsules USP 100mg**

Each Softgel Contains:  
(Docosate Sodium USP 100mg)

LOT NO	:	QUANTITY	:
DRUM NO	:	NDC NO	: 68210-0401-*
MFG DATE	:	EXP DATE	:

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## DOCUSATE SODIUM

docosate sodium capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0401
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
D&C RED No. 33 (UNII: 9DBA0SBB0L)	
FD&C RED No. 40 (UNII: WZB9127XOA)	

**Product Characteristics**

<b>Color</b>	RED	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	DO4
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0401-1	10 in 1 BOX		
2	NDC:68210-0401-2	30 in 1 BOX		
3	NDC:68210-0401-3	100 in 1 BOX		
4	NDC:68210-0401-4	1000 in 1 BOX		
5	NDC:68210-0401-5	16000 in 1 BOX		
6	NDC:68210-0401-6	20000 in 1 BOX		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/01/2010	

**Labeler** - SPIRIT PHARMACEUTICALS,LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
SOFTGEL HEALTHCARE PVT LTD		675584180	MANUFACTURE