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.

DOCUSATE SODIUM CAPSULES USP 50 MG

Drug Facts

Active ingredient
(in each capsule)

Docusate sodium 50 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 1-6 capsules daily

children 2 to under 12 years of age	take 1-3 capsules daily
children under 2 years	ask a doctor

Inactive ingredients

D&C Red No. 33, FD&C Red No. 40, gelatin, glycerin, PEG 400, propylene glycol, sorbitol

Questions? 1-888-726-7535
(8am-5pm, EST, Mon.-Fri.).

PRINCIPAL DISPLAY PANEL

Docusate Sodium capsules USP 50mg
Each Softgel Contains:
(Docusate Sodium USP 50mg)

LOT NO :

DRUM NO :

MFG DATE :

QUANTITY :

NDC NO : 68210-0402-

EXP DATE :

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.

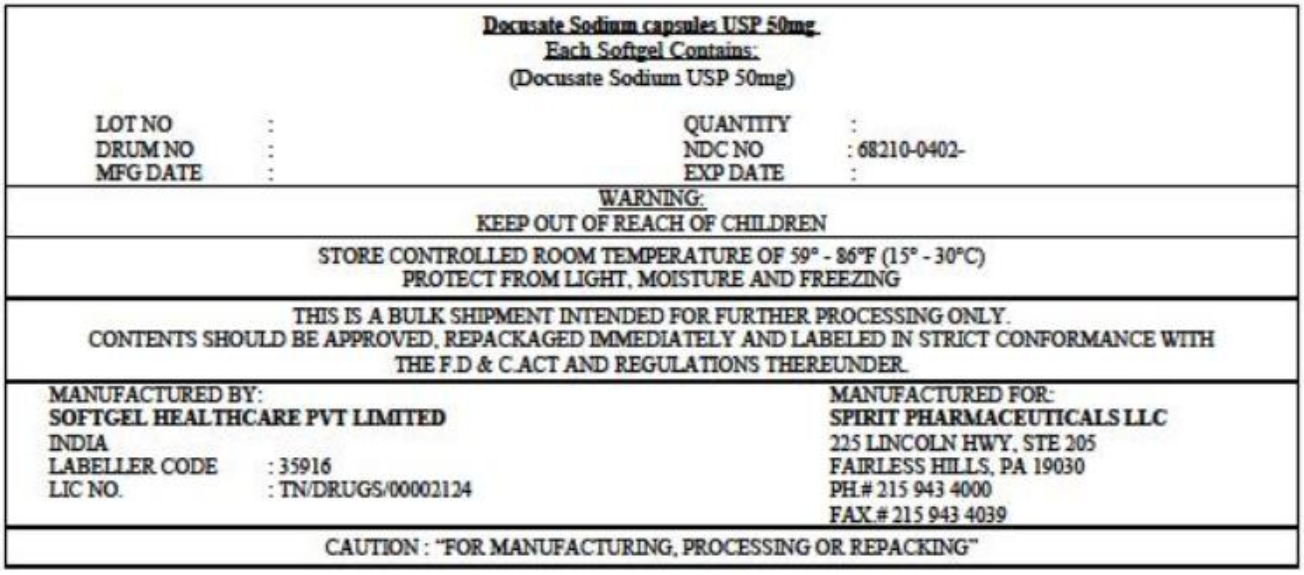
MANUFACTURED BY:
SOFTGEL HEALTHCARE PVT LIMITED
INDIA
LABELLER CODE : 35916
LIC NO. : TN/DRUGS/00002124

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



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DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0402
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	DO4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0402-1	1 in 1 BOX		
1		10 in 1 BAG		
2	NDC:68210-0402-2	1 in 1 BOX		
2		30 in 1 BAG		
3	NDC:68210-0402-3	1 in 1 BOX		
3		100 in 1 BAG		
4	NDC:68210-0402-4	1 in 1 BOX		
4		1000 in 1 BAG		
5	NDC:68210-0402-5	1 in 1 BOX		
5		16000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part310.545	10/01/2009	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Establishment

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

Revised: 11/2009 SPIRIT PHARMACEUTICALS,LLC