

DOCUSATE SODIUM 100MG- docusate sodium 100mg- docusate sodium capsule, liquid filled capsule, liquid filled SHANDONG ROSEMED BIOOHARM LLC

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are presently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. 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.

Directions

take with a glass of water

adults and children 12 years and over	1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses.
children 2 and under 12 years of age	1 softgel daily
children under 2 years of age	ask a doctor

Other information

- each softgel contains: sodium 5 mg
- store at room temperature 15°-30°C (59°-86°F)
- protect from excessive humidity

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special, citric acid, purified water and white edible ink

Dosage & administration

each softgel contains: sodium 5 mg
store at room temperature 15°-30°C (59°-86°F)
protect from excessive humidity

Indications & usage section

adults and children 12 years and over	1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses.
children 2 and under 12 years of age	1 softgel daily
children under 2 years of age	ask a doctor

keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Label Information

DOCUSATE SODIUM CAPSULES, 100 mg

Quantity : 20000 Capsules

NDC. No : 84328-001

IMPORTANT:

Inspect immediately upon receipt.

This is a bulk shipment, intended for further processing only.

Protect from heat, humidity, and light. Do not refrigerate.

Store at 15-30°C (59-86°F)

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product:

Docusate Sodium Capsules 100 mg

Each softgel contains: Docusate Sodium 100 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

43-01655

Quantity:

20000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

xx/yyyy

Box No.:

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 15-30°C (59-86°F)

MADE IN CHINA

DOCUSATE SODIUM 100MG

docusate sodium 100mg- docusate sodium capsule, liquid filled capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84328-001
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	red	Score	score with uneven pieces
Shape	CAPSULE (OVAL)	Size	13mm
Flavor		Imprint Code	655
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84328-001-01	1 in 1 BOX	05/16/2024	
1		20000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:84328-001-02	1 in 1 BOX	05/17/2024	
2		15000 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	05/16/2024	

Labeler - SHANDONG ROSEMED BIOOHARM LLC (416829348)

Registrant - SHANDONG ROSEMED BIOOHARM LLC (416829348)

Establishment

Name	Address	ID/FEI	Business Operations
SHANDONG ROSEMED BIOOHARM LLC		416829348	manufacture(84328-001)

Revised: 8/2024

SHANDONG ROSEMED BIOOHARM LLC