

DOCUSATE SODIUM 100MG- docusate sodium capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.

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 100mg, Capsule, liquid filled

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.

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

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

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.
Wuhan, Hubei 430206,
China

PRINCIPAL DISPLAY PANEL - Shipping Label**DOCUSATE SODIUM CAPSULES, 100 mg**

Quantity : 20000 Capsules

NDC. No : 53345-029-01

IMPORTANT:

1. Inspect immediate 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)

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Hunanwell PuraCap Pharmaceutical (Wuhan) Ltd.

No. 99, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-029-01

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

**REV-00
10/2014**

DOCUSATE SODIUM CAPSULES, 100 mg

Quantity : 15000 Capsules

NDC. No : 53345-029-02

IMPORTANT:

1. Inspect immediate 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)

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

No. 99, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-029-02

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:

15000 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

**REV-01
03/2015**

DOCUSATE SODIUM 100MG

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-029
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg
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Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE (OVAL)	Size	13mm
Flavor		Imprint Code	655
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-029-01	1 in 1 BOX		
1		20000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:53345-029-02	1 in 1 BOX		
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 not final	part334	01/28/2015	

Labeler - Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd. (421293287)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	MANUFACTURE(53345-029) , ANALYSIS(53345-029)

Revised: 4/2015

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.