

**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.*

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**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:**

Inspect immediate 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**

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**Hunanwell PuraCap Pharmaceutical (Wuhan) Ltd.**

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

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**NDC No.: 53345-029-01**

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Product:

**Docusate Sodium Capsules 100 mg**

Each softgel contains: Docusate Sodium 100 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

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Product Code:

43-01655

Quantity:

20000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

xx/yyyy

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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**

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**REV-00**

**10/2014**

**PRINCIPAL DISPLAY PANEL - Shipping Label**

DOCUSATE SODIUM CAPSULES, 100 mg

Quantity : 15000 Capsules

NDC. No : 53345-029-02

**IMPORTANT:**

Inspect immediate 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

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**Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.**

No. 99, 2nd Shendun Road, East Lake New Technology Development District,

Wuhan, Hubei 430206, P. R. China

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**NDC No.: 53345-029-02**

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Product:

**Docusate Sodium Capsules 100 mg**

Each softgel contains: Docusate Sodium 100 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

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Product Code:

43-01655

Quantity:

15000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

xx/yyyy

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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**

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**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

<b>Route of Administration</b>	ORAL
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### 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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

### Product Characteristics

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

### Packaging

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

