

**DOCUSATE SODIUM- docusate sodium capsule, liquid filled**  
**Humanwell PuraCap Pharmaceuticals (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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**Drug Facts**

**Active ingredient (in each softgel)**

Docusate sodium 250 mg

**Purpose**

Stool softener laxative

**Uses**

- for the prevention of dry, hard stools
- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

**Warnings**

**Do not use**

if you are presently taking mineral oil, unless directed by a doctor.

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

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last 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**

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

**Other information**

- **each softgel contains: sodium 15 mg**
- store at 20°-25°C(68°-77°F); excursions permitted between 15°-30°C (59°-86°F)

### **Inactive Ingredients**

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

Manufactured by:

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

### **Principal Display Panel - Shipping Label**

Docusate Sodium Capsules

250 mg

NDC 53345-035-01

7000 Capsules

**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)

**CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING"**

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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.: 53345-035-01**

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Product:

## **Docusate Sodium Capsules 250 mg**

Each softgel contains: Docusate Sodium 250 mg

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

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Product Code:

40-00031

Quantity:

7000 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  
11/2015**

### **DOCUSATE SODIUM**

docusate sodium capsule, liquid filled

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-035

Route of Administration

ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

**Inactive Ingredients**

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	red (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	P4
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-035-01	1 in 1 BOX	02/10/2016	
1		7000 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	02/10/2016	

**Labeler** - Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd (421293287)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(53345-035) , analysis(53345-035)