

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

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener

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 to 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) Ltd.

Wuhan, Hubei

430206, China

PRINCIPAL DISPLAY PANEL - Shipping Label

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-008-01

Product:

DOCUSATE SODIUM CAPSULES, 100 MG

Each softgel contains: Docusate Sodium USP, 100 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 40-00004	Quantity: 20000 Capsules
Lot No.: 0000000	Manufacturing Date: 00/0000
Box No.: X	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.
MADE IN CHINA	

REV - 00
03/2013

DOCUSATE SODIUM CAPSULES, 100 mg
Quantity : 15000 Capsules
NDC. No : 53345-008-02

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.

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

PRINCIPAL DISPLAY PANEL - Shipping Label

DOCUSATE SODIUM CAPSULES, 100 mg
Quantity : 15000 Capsules
NDC. No : 53345-008-02

IMPORTANT:

1. Inspect immediately upon receipt.

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

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-008-02

Product:

Docosate Sodium Capsules 100 mg

Each softgel contains: Docosate Sodium 100 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00004

Quantity:

15000 Capsules

Lot Number:

xxxxxxx

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-02
03/2015

DOCUSATE SODIUM

docosate sodium capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-008

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
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE (OVAL)	Size	13mm
Flavor		Imprint Code	PC1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-008-01	1 in 1 BOX	04/15/2013	
1		20000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:53345-008-02	1 in 1 BOX	04/15/2013	
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	M007	04/15/2013	

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-008)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.