

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

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"

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-035-01

Product:

Docosate Sodium Capsules 250 mg

Each softgel contains: Docosate Sodium 250 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00031

Quantity:

7000 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
11/2015**

DOCUSATE SODIUM

docosate 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 Drug	M007	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)

