

DOCUSATE SODIUM 100MG TWO-TONE- 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

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 12 to 72 hours

Warnings

Do not use

- if you are presently taking mineral oil, unless told to do so by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel movements that lasts 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 stool softener 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 only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- each softgel contains: **sodium 5 mg**
- **VERY LOW SODIUM**
- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive ingredients

Black ink, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special and purified water

Manufactured by:

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

PRINCIPAL DISPLAY PANEL - Shipping Label

DOCUSATE SODIUM CAPSULES, 100 mg
Quantity : 20000 Capsules
NDC. No : 53345-018-01

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

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-018-01

Product:

DOCUSATE SODIUM CAPSULES, 100 MG

Each softgel contains: Docusate Sodium USP, 100 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 40-00012	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
10/2013

DOCUSATE SODIUM CAPSULES, 100 mg

Quantity : 15000 Capsules

NDC. No : 53345-018-02

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.
4. Store at 15-30°C (59-86°F)

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.
No. 99, 2nd Shendum Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-018-02

Product:

Docosate Sodium Capsules 100 mg

Each softgel contains: Docosate Sodium 100 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00012

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-02
02/2015

DOCUSATE SODIUM 100MG TWO-TONE

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-018
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA05BB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red, white (Two-Tone)	Score	no score
Shape	CAPSULE (OVAL)	Size	13mm
Flavor		Imprint Code	PC18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-018-01	1 in 1 BOX	12/23/2013	
1		20000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:53345-018-02	1 in 1 BOX	12/23/2013	
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	12/23/2013	

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

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-018)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.