DOCUSATE SODIUM 100MG TWO-TONE- docusate sodium capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan), 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.

DOCUSATE SODIUM 100mg Two-Tone, Capsule, liquid filled

Drug Facts

Active ingredient (in each capsule)

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 currently 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 using 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 of ages and over	take 1 to 3 softgels daily
Children 2 and under 12 years of age	take 1 softgel daily
children under 2 years of	

children under 2 years of age	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

D&C Red #33, 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

DOCUSATE SODIUM CAPSULES, 100 mg

Quantity : 20000 Capsules
NDC. No : 53345-023-01

IMPORTANT:
1.Inspect immediate 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.: 53345-023-01

Product:

Docusate Sodium Capsules 100 mg

Each softgel contains: Docusate Sodium 100 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 43-01657

Quantity: 20000 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℃ (59-86℉)
MADE IN CHINA	

REV-00
07/2014

DOCUSATE SODIUM 100MG TWO-TONE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53345-023
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
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, white (Two-Tone)	**Score**	no score
Shape	CAPSULE (OVAL)	**Size**	13mm
Flavor		**Imprint Code**	657
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53345-023-01	1 in 1 BOX	08/11/2014	
1		20000 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	08/11/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	MANUFACTURE(53345-023) , ANALYSIS(53345-023)

Revised: 11/2019 Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.