DOCUSATE SODIUM- 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, Capsule, liquid filled

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 vomitting
- 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:	Quantity:
40-00004	20000 Capsules
Lot No.:	Manufacturing Date:
0000000	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.

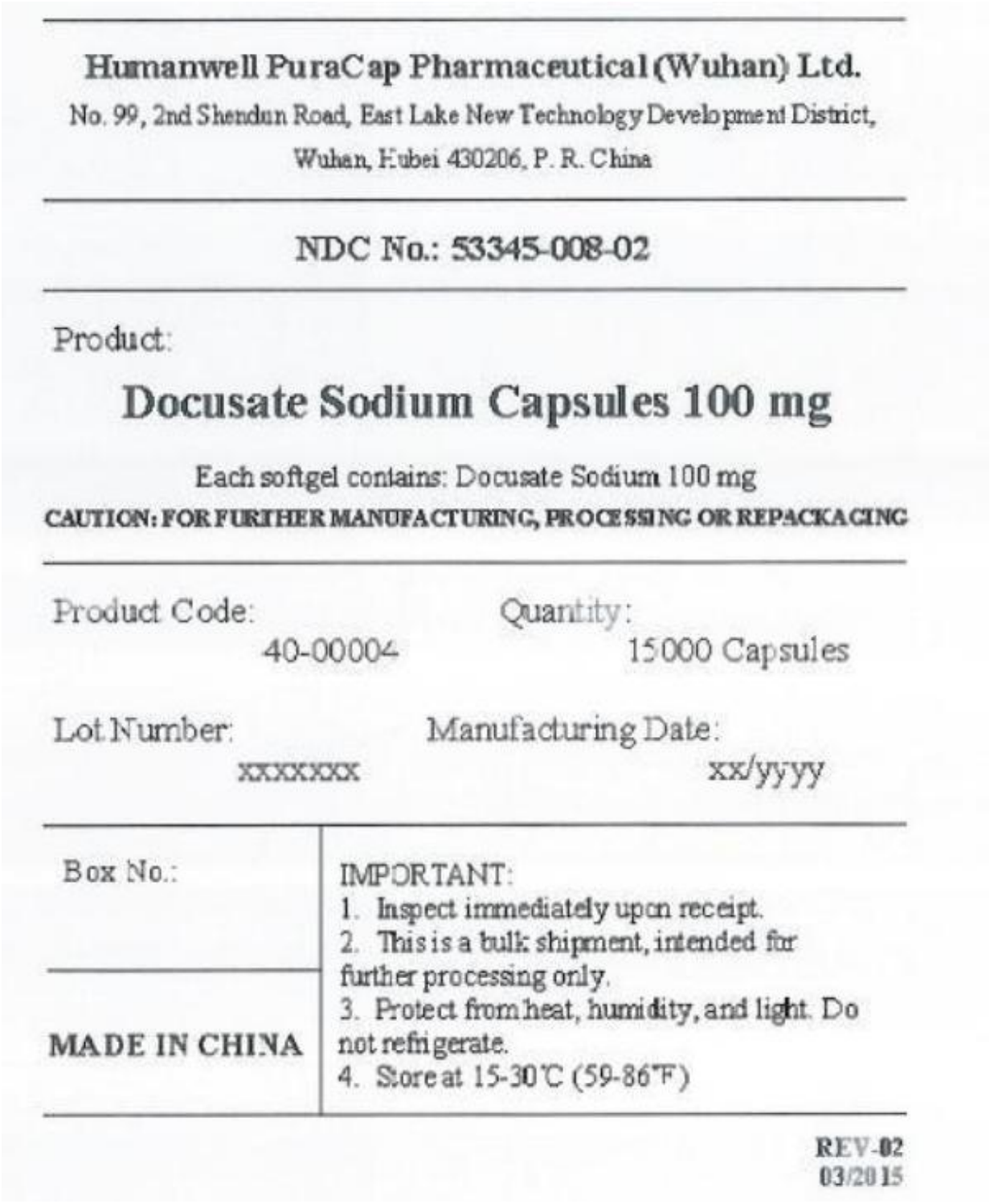
CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

PRINCIPAL DISPLAY PANEL - Shipping Label

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

IMPORTANT:
1.Inspect immediately upon receipt.
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



DOCUSATE SODIUM

docusate 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 not final	part334	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) , ANALYSIS(53345-008)