STOOL SOFTENER- docusate sodium capsule, liquid filled
PuraCap Pharmaceutical LLC

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.

STOOL SOFTENER

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

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

citric acid, FD&C red # 40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special and white edible ink

Questions or comments?

Call toll free: 1-800-833-6278

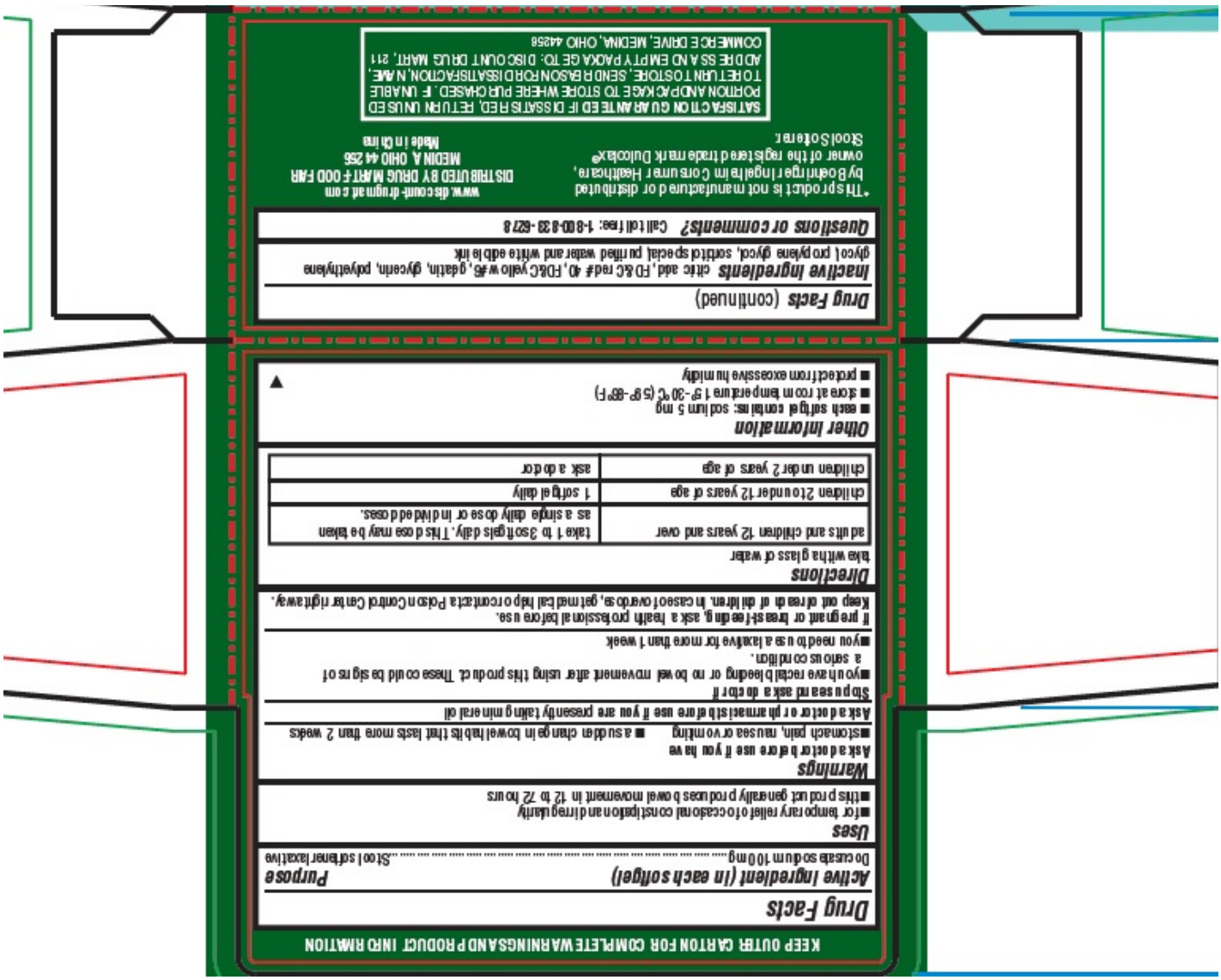
Principal Display Panel

STOOL SOFTENER

DOCUSATE SODIUM 100mg 100 SOFTGELS

Compare to the active ingredient in DULCOLAX®

NDC 51013-120-24



STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-120
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)	
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 (oval)	**Size**	13mm
Flavor		**Imprint Code**	PC1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-120-24	1 in 1 CARTON	10/02/2016	
1		100 in 1 BOTTLE; 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	10/02/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-120) , analysis(51013-120)