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 relief of occasional constipation (irregularity)
- this product generally produces a 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 over 14 days

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 softgels with a full glass (8oz) of water

adults and children 12 years and older	take 1 to 3 softgels daily or as directed by a doctor. This dose may be taken as a single daily dose or in divided doses.
children 6 to under 12 years	take 1 softgel daily or as directed by a doctor
children under 6 years	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

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

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Stool Softener

DOCUSATE SODIUM 100 mg 30 SOFTGELS

Compare to Phillips' Stool Softener Liquid Gels active ingredient

NDC 51013-433-20

NDC 51013-433-20

*Compare to the active ingredient in Phillips'® Stool Softener Liquid Gels

Stool Softener Laxative

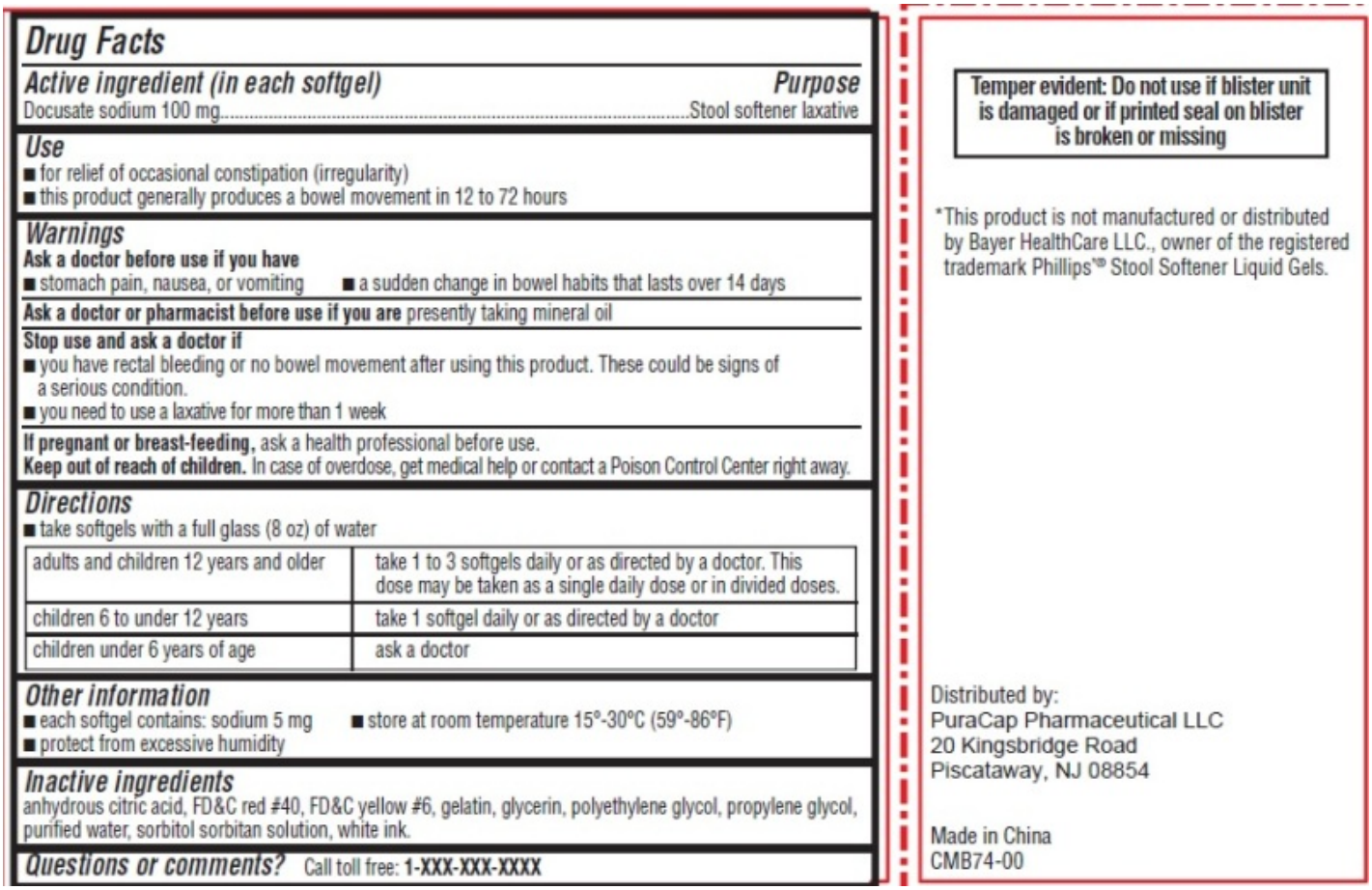
Docusate Sodium 100 mg / Laxative

- Effective relief of constipation

Stimulant free
Cramp free
Gentle, dependable relief
Easy to swallow

Actual Size

30 SOFTGELS
1 Bottle inside



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Questions or comments? Call toll free: 1-XXX-XXX-XXXX

Temper evident: Do not use if blister unit is damaged or if printed seal on blister is broken or missing

*This product is not manufactured or distributed by Bayer HealthCare LLC., owner of the registered trademark Phillips'® Stool Softener Liquid Gels.

Distributed by:
PuraCap Pharmaceutical LLC
20 Kingsbridge Road
Piscataway, NJ 08854

Made in China
CMB74-00

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-433
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)	
SORBITAN (UNII: 6O92ICV9RU)	

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:51013-433-20	1 in 1 CARTON	03/29/2018	
1		30 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	03/29/2018	

Labeler - PURACAP PHARMACEUTICAL LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-433) , analysis(51013-433)

Revised: 1/2020 PURACAP PHARMACEUTICAL LLC