

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 250 mg

Purpose

Stool softener laxative

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless directed by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last 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 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

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- each softgel contains: sodium 15 mg
- store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)

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 250mg 100 SOFTGELS

Compare to the active ingredient in COLACE®

NDC 51013-194-24

Drug Facts

Active ingredient (in each softgel)
Docosate sodium 100 mg. Stool softener.

Purpose
Stool softener.

Uses
relieves occasional constipation (irregularity)
generally produces 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 habits 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 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 D&C red #35, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol, sorbitic acid, purified water and black edible ink.

Questions or comments? Call toll free: 1-800-933-8278

*This product is not manufactured or distributed by Purdue Pharma, L.P., owner of the registered trademark "Colace".

SATISFACTION GUARANTEED
IF UNSATISFIED, RETURN UNOPENED PACKAGE TO STORE WHERE PURCHASED. PACKAGE MUST BE UNOPENED AND ORIGINAL RECEIPT MUST ACCOMPANY PACKAGE TO: DISCOUNT DRUG MART, 611 COMMERCIAL DR., MEDINA, OHIO 44130
www.discount-drugmart.com
MADE IN CHINA

DDM03-02
LOT NO: 0 93351-01022 4
EXP. DATE:

STOOL SOFTENER

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-194
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 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: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	red (clear)	Score	no score
Shape	capsule (oval)	Size	20mm
Flavor		Imprint Code	P4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-194-24	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/14/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-194) , analysis(51013-194)

Revised: 1/2020

PuraCap Pharmaceutical LLC