

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 51013-814-24

PuraVation. NDC 51013-814-24
Compare to the active ingredient in COLACE® Stool Softener¹

Extra Strength
Stool Softener
DOCUSATE SODIUM 250 mg
• Relieves Constipation
• Stimulant Free
100 Softgels
Actual Size

Drug Facts
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING
Active ingredient (in each softgel) Docusate sodium 250 mg Stool softener, laxative

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Questions or comments? Call toll free: 1-855-215-8180
*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace® Stool Softener.

DISTRIBUTED BY:
PURACAP PHARMACEUTICAL LLC
ISELIN, NJ 08830
MADE IN CHINA
PC85-00

LOT NO:
EXP. DATE:

3 51013 81424 6

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51013-814

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: 059QF0KO0R)	
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:51013-814-24	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/07/2021	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co.,		421202207	manufacture(51013-814) , analysis(51013-

Ltd.

421295201 814)

Revised: 5/2021

PuraCap Pharmaceutical LLC