

STOOL SOFTENER DOCUSATE SODIUM 50 MG- 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 DOCUSATE SODIUM 50mg, Capsule, liquid filled

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 50 mg

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 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 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 6 softgels daily
Children 2 to	

under 12 years of age	take 1 to 3 softgels daily
children under 2 years	ask a doctor

Other information

- each softgel contains: **sodium 3 mg**
VERY LOW SODIUM
- store at 15°-30°C (59°-86°F)
Keep tightly closed.

Inactive ingredients

citric acid, D&C red #33, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special, white edible ink

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.
Wuhan, Hubei 430206,
China

PRINCIPAL DISPLAY PANEL - 30ct

STOOL SOFTENER NDC 51013-111-20

Compare to the active ingredient in Colace® 50 mg

50 MG DOCUSATE SODIUM PER SOFTGEL 30 Softgels



CVS Health. NDC 51013-111-20

Stool Softener

DOCUSATE SODIUM
50 mg

- Stimulant free
- Gentle & effective

30 SOFTGELS

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Purpose	Docusate sodium 50 mg.....Stool softener						
Active ingredient (in each softgel)	Docusate sodium 50 mg.....Stool softener						
Uses	<ul style="list-style-type: none"> ■ relieves occasional constipation (irregularity) ■ generally produces bowel movement in 12 to 72 hours 						
Warnings	<p>KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>						
Directions	<p>Take only by mouth. Doses may be taken as a single daily dose or in divided doses.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years and over</td> <td>take 1 to 6 softgels daily</td> </tr> <tr> <td>children 2 to under 12 years of age</td> <td>take 1 to 3 softgels daily</td> </tr> <tr> <td>children under 2 years</td> <td>ask a doctor</td> </tr> </table>	adults and children 12 years and over	take 1 to 6 softgels daily	children 2 to under 12 years of age	take 1 to 3 softgels daily	children under 2 years	ask a doctor
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LOT: CV501-03
EXP:

PRINCIPAL DISPLAY PANEL - 100ct
STOOL SOFTENER NDC 51013-111-24

Compare to the active ingredient in Colace® 50 mg
 50 MG DOCUSATE SODIUM PER SOFTGEL 100 Softgels

CVS Health.

Stool Softener
DOCUSATE SODIUM, 50 mg

- Stimulant free
- Gentle & effective

Compare to the active ingredient in Colace®*
NDC 51013-111-24

Stool Softener
DOCUSATE SODIUM, 50 mg

- Stimulant free
- Gentle & effective
- Comfortable relief of constipation

Actual Size

100 SOFTGELS

Drug Facts

Active ingredient (in each softgel) Docusate sodium 50 mg	Purpose Stool softener
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Uses

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SAVE CARTON FOR COMPLETE DRUG FACTS.

Drug Facts (continued)

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Questions or comments? Call: 1-855-215-8180

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Money Back Guarantee

V-31141

CVS Health.

Compare to the active ingredient in Colace®*
NDC 51013-111-24

Stool Softener
DOCUSATE SODIUM, 50 mg

- Stimulant free
- Gentle & effective
- Comfortable relief of constipation

100 SOFTGELS

#696215



0 50428 25328 1

CVS04-03

LOT NO: COATING
EXP DATE: FREE AREA

CVS Health.

NDC 51013-111-24

Stool Softener
DOCUSATE SODIUM, 50 mg

- Stimulant free
- Gentle & effective

100 SOFTGELS

Active ingredient (in each softgel)
Docusate sodium 50 mg

Purpose
Stool softener

Uses

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Warnings

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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CVS03-03

LOT NO:
EXP DATE:

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

STOOL SOFTENER DOCUSATE SODIUM 50 MG

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
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 (clear)	Score	no score
Shape	CAPSULE (OVAL)	Size	13mm
Flavor		Imprint Code	PC20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-111-20	1 in 1 CARTON	08/22/2014	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:510 13-111-24	1 in 1 CARTON	08/22/2014	
2		100 in 1 BOTTLE, PLASTIC; 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	08/22/2014	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	analysis(510 13-111) , manufacture(510 13-111)

Revised: 12/2019

PuraCap Pharmaceutical LLC