

**STOOL SOFTENER DOCUSATE SODIUM 50 MG- docusate sodium capsule, liquid filled
CVS PHARMACY, INC.**

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 Carton and Bottle Label

STOOL SOFTENER DOCUSATE SODIUM 50 MG 30ct

NDC 69842-072-20

Compare to the active ingredient in Colace[®] 50 mg



<p>CVS Health. Compare to the active ingredient in Colace® NDC 51013-111-20</p> <h1>Stool Softener</h1> <p>DOCUSATE SODIUM 50 mg</p> <ul style="list-style-type: none"> Stimulant free Gentle & effective <p>30 SOFTGELS</p>	<p>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING</p>	<p>Purpose Docusate sodium 50 mg.....Stool softener</p>	<p>Uses relieves occasional constipation (irregularly) generally produces bowel movement in 12 to 72 hours</p>	<p>Warnings KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION 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.</p>	<p>Directions Take only by mouth. Doses may be taken as a single daily dose or in divided doses.</p> <table border="1"> <tr> <td>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	<p>Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2015 CVS/pharmacy CVS.com® 1-800-SHOP CVS Made in China V-31141 LOT: CV501-03 EXP:</p>
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											

PRINCIPAL DISPLAY PANEL - 100ct Carton and Bottle Label

STOOL SOFTENER DOCUSATE SODIUM 50 MG 100ct

NDC 69842-072-24

Compare to the active ingredient in Colace® 50 mg

CVS Health.

Stool Softener

DOCUSATE SODIUM, 50 mg

- Stimulant free
- Gentle & effective

Drug Facts

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

Actual Size

100 SOFTGELS

SAVE CARTON FOR COMPLETE DRUG FACTS.

Drug Facts (continued)

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Questions or comments? Call 1-855-215-8100

*This product is not manufactured or distributed by Parke Products L.P., owner of the registered trademark Colace®.

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CVS Quality
Money Back Guarantee

7-31141

CVS Health. Compare to the active ingredient in Colace®
NDC 51013-111-24

Stool Softener

DOCUSATE SODIUM, 50 mg

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Drug Facts (continued)

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NDC 51013-111-24

Stool Softener

DOCUSATE SODIUM, 50 mg

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- Gentle & effective
- Comfortable relief of constipation

Actual Size

100 SOFTGELS

#696215



0 50428 25328 1

CVS04-03

LOT NO: COATING
EXP DATE: FREE AREA

CVS Health.

Stool Softener

DOCUSATE SODIUM, 50 mg

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Actual Size

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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NDC 51013-111-24

Stool Softener

DOCUSATE SODIUM, 50 mg

- Stimulant free
- Gentle & effective

Actual Size

100 SOFTGELS

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

CVS Quality
Money Back Guarantee

CVS03-03

LOT NO:
EXP DATE:

STOOL SOFTENER DOCUSATE SODIUM 50 MG

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-072
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: 059QF0K00R)	
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:69842-072-20	1 in 1 CARTON	12/14/2016	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69842-072-24	1 in 1 CARTON	12/14/2016	
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	12/14/2016	

Labeler - CVS PHARMACY, INC. (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	analysis(69842-072) , manufacture(69842-072)

Revised: 11/2019

CVS PHARMACY, INC.