STOOL SOFTENER PLUS LAXATIVE- docusate sodium, sennosides tablet QUALITY CHOICE (Chain Drug Marketing Association)

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.

DRUG FACTS

Active Ingredients (in each tablet)

Docusate Sodium 50 mg Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Purpose

Stool softener

laxative

Uses

- relieves occasional constipation (irregularity)
- generally causes bowel movement in 6- 12 hours.

Warnings

Do not use

- If you are now taking mineral oil, unless directed by a doctor
- · laxative products for longer than 1 week 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 continues over a period of 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 may indicate a serious condition.

If pregnant or breastfeeding,

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 preferably at bedtime or as directed by a doctor

age	starting dosage	maximum dosage
adults and children 12 years of age and older	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains: calcium 20 mg
- each tablet contains: sodium 6 mg VERY LOW SODIUM
- store at 25°C (77°); excursions permitted between 15°-30°C (59°-86°F)

Inactive Ingredients

carnauba wax, croscarmellose sodium, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake*, FD&C red #40 aluminum lake*, FD&C yellow #6 aluminum lake, hypromellose*, magnesium stearate, maltodextrin*, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol*, silicon dioxide, sodium benzoate, stearic acid, talc* and titanium dioxide.

*contains one or more of these ingredients

Questions or comments?

call 1-248-449-9300 Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredients in Senokot-S®

Stool Softener plus laxative

Stool Softener • Laxative

Docusate Sodium, 50 mg/ Sennosides, 8.6 mg Provides Gentle Relief of: Occasional Constipation

Tablets

†This product is not manufactured or distributed by Purdue Products L.P., owner of the

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP ID BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by C.D.M.A., Inc© 43157 W. Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com

Product Label









SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEP DUTER CARTON FOR COMPLETE
MADMANCE AND BORDHITT WEDDAMATTON

This product is not manufactured or distributed by Purdue Products L.P., distributor of Senokot-S®.

Questions or comments? Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

Inactive ingredients canaube wax", croscamellose sodium, D&C yellow #10 aluminum lake, dibasic calcium phosphate othydrate, TD&C blue #2 aluminum lake, hypomellose, polyethylene glycol, polywinyl alcohol*, hypomellose, polyethylene glycol, polywinyl alcohol*, alicon dioxide, sodium benzoate*, aleane acid, talc*, titanium dioxide calcium penzoate*, aleane acid, talc*, titanium dioxide calcium cone or more or these ingredients

Drug Facts (continued)

anolocad s suchden change in bowel habits that continues over a period of 2 weeks. Stop use as task a doctor if you have rectal bleeding or may indicate a serious condition. If pregnant or breast-feeding, sak a health professional pelore use.	itsmrofriitsmoth	ns: calcium 20 mg n s: sodium 6 mg	WINDOS MOT
Ask a doctor before use if you have ■ stomach pain ■ nausea ■ vomiting	children under 2 years	ssk s doctor	sak a doctor
på s doctor ■ Isxstjye broducts for longer than 1 week unless directed	children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
Do not use II if you are now taking mineral oil, unless directed by a doctor	children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
sgnimeW esu ton of	children 12 years of age and over	оисе в дай	twice a day
■ generally produces bowel movement in 6-12 hours	adults and	2 tablets	4 tablets
Uses relieves occasional constipation (irregularity)	986	starting dosage	mumixem egesob
orusate sodium 50 mg	■ take preferably at b	edtime or as direc	ted by a doctor
Active ingredients Purpose (in each tablet)	Keep out of reach of children. In case of overdose, get medical help or contact a Polson Control Center right away.		
Drug Facts	Drug Facts (continued)		

Quality Choice Stool Softener Orange Tablets

STOOL SOFTENER PLUS LAXATIVE

docusate sodium, sennosides tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-137
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	
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL081;0805;AV;S35
Contains			

	Packaging		
- 1		54 1 1' CI I	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-137- 60	1 in 1 BOX	11/30/2015	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Marketing Start Category Citation Date			Marketing End Date
OTC monograph not final	part334	11/30/2015	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2022 QUALITY CHOICE (Chain Drug Marketing Association)