STOOL SOFTENER LAXATIVE- docusate sodium and sennosides tablet TOP CARE (Topco Associates LLC)

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg Sennosides 8.6 mg

Purpose

Stool softener

Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- 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 lasts 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 could be signs of a serious condition.

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, preferably in the evening, or in divided doses.

adults and children 12 years and older	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2	ask a doctor

Other information

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

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, talc*, titanium dioxide

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO COLACE® 2-IN-1 ACTIVE INGREDIENT†

Stool Softener

Plus Stimulant Laxative

DOCUSATE SODIUM 50 mg STOOL SOFTENER

SENNOSIDES 8.6 mg STIMULANT LAXATIVE

For Overnight Relief Of Occasional Constipation

- Effective
- Reliable
- Comfortable

TABLETS

GLUTEN FREE

†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® 2-IN-1

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.comwww.topcarebrand.com

Product Label



Lot No.: Exp. Date:

Drug Facts Active ingredients Purpose (in each tablet) Docusate sodium 50 mg. Stool softener Sennosides 8.6 mg. Stimulant laxative relieves occasional constipation (irregularity) ■ generally produces bowel movement in 6 to 12 hours Warnings Do not use ■ laxative products for longer than 1 week unless directed by a doctor 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 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 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, preferably in the evening, or in divided

adults and children 12 years and over	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2	ask a doctor
store at 25°C (77°F); ex 15-30°C (59-86°F)	cursions permitted between ts croscarmellose sodium,
■ each tablet contains: s ■ store at 25°C (77°F); exi 15-30°C (59-86°F) Inactive ingredient dibasic calcium phosphate aluminum lake, FD&C red hypromellose, magnesium	codium 6 mg VERY LOW SODIUM cursions permitted between ts croscarmeliose sodium, dihydrate, FD&C blue #2
■ each tablet contains: s ■ store at 25°C (77°F); exi 15-30°C (59-86°F) Inactive ingredient dibasic calcium phosphate aluminum lake, FD&C red hypromellose, magnesium	todium 6 mg VERY LOW SODIUM cursions permitted between to consider the construction of

Scan here for more

information or

call 1-888-423-0139

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP

IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR

COMPLETE WARNINGS AND

PRODUCT INFORMATION.

STOOL SOFTENER LAXATIVE

docusate sodium and sennosides tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-555

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) SENNOSIDES (Basis of Strength Str

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	PSD21
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800- 555-10	1 in 1 BOX	07/30/2020	
1		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 Drug	M007	07/30/2020	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Registrant - P & L Development, LLC (079765031)

Revised: 10/2023 TOP CARE (Topco Associates LLC)