STOOL SOFTENER LAXATIVE- docusate sodium and sennosides tablet WinCo Foods, 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.

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 to12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are now 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 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 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 21 mg
- each tablet contains: sodium 5 mg VERY LOW SODIUM
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

carnauba wax, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium benzoate, stearic acid, titanium dioxide

Questions or comments?

Call **1-800-824-1706** Monday-Friday 9AM-4PM MST

Principal Display Panel

**Compare to the active ingredients in Colace®2-IN-1

Stool Softener

& Stimulant Laxative

DOCUSATE SODIUM 50 mg/

STOOL SOFTENER

SENNOSIDES 8.6 mg/

STIMULANT LAXATIVE

Dependable relief in 6-12 hours

Tablets

**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.

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

Product Label



WINCO FOODS Stool Softener Laxative

STOOL SOFTENER LAXATIVE docusate sodium and sennosides tablet Product Information Product Type HUMAN OTC DRUG Route of Administration HUMAN OTC DRUG 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)		
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)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
ALUMINUM OXIDE (UNII: LMI2606933)		

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL097
Contains			

P	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:67091- 374-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/30/2020		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/30/2020	

Labeler - WinCo Foods, LLC (056098817)

Revised: 10/2023 WinCo Foods, LLC