

COLACE- docusate sodium - sennosides tablet, film coated
Avrio Health L.P.

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.

Colace

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 told to do so 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 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 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

Other information

- each tablet contains: **calcium 7 mg, sodium 4 mg VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Inactive ingredients

Croscarmellose sodium, dicalcium phosphate, FD&C Blue #1 Lake, FD&C Red #40 Lake, FD&C Yellow #6 Lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacetin

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Avrio Health L.P.

305604-0A

Colace 2-In-1
10 Tablets

#1 Doctor Recommended
Stool Softener Brand

Plus Stimulant Laxative

Formerly Peri-Colace

COLACE[®]
Docusate Sodium
Sennosides

2-IN-1

**Stool Softener +
Stimulant Laxative**

- Gentle, Dependable
- Relief in 6-12 Hours

10 Tablets

COLACE

docusate sodium - sennosides tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-110
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	RED (burgundy)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	P;054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-110-10	2 in 1 CARTON	02/08/1957	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:67618-110-30	1 in 1 CARTON	02/08/1957	
2		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:67618-110-60	1 in 1 CARTON	02/08/1957	
3		60 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	02/08/1957	

Labeler - Avrio Health L.P. (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		968334974	MANUFACTURE(67618-110)

Revised: 12/2021

Avrio Health L.P.