COLACE- docusate sodium - sennosides tablet, film coated Atlantis Consumer Healthcare, Inc.

Colace

Drug Facts

Active ingredient	Purpose	
Docusate	Stool	
sodium 50 mg	softener	
Sennosides 8.6	Stimulant	
mg	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 ifyou 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	take up to 1
years of age	tablet daily
children under 2	ask a doctor

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).
 Keep tightly closed..

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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A1023

R52504

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

#1
DOCTOR
RECOMMENDED
Stool Softener Brand

Colace ®

Docusate Sodium, 50 mg Sennosides 8.6 mg

2-IN-1

Stool Softener + Stimulant Laxative

√ Gentle, Effective, & Dependable√ Constipation Relief in 6 `12 hours

10Tablets



Colace® 2-IN-1 Tablets

Docusate Sodium Sennosides Dist. by: Atlantis Consumer Healthcare Inc.

LOT XXXXXX EXP YYYY-MM

Colace® 2-IN-1 Tablets

Docusate Sodium

Sennosides

Dist. by: Atlantis Consumer

Healthcare Inc.

LOT XXXXXX EXP YYYY-MM

Colace® 2-IN-1 Tablets

Docusate Sodium

Sennosides

Dist. by: Atlantis Consumer

Healthcare Inc.

LOT XXXXXX EXP YYYY-MM

Colace® 2-IN-1 Tablets

Docusate Sodium

Sennosides

Dist. by: Atlantis Consumer

Healthcare Inc.

LOT XXXXXX

EXP YYYY-MM

Dist. by:

Atlantis Consumer Healthcare Inc.

Bridgewater, NJ 08807

Colace® 2-IN-1 Tablets

Docusate Sodium

Sennosides

Dist. by: Atlantis Consumer

Healthcare Inc.

LOT XXXXXX EXP YYYY-MM

Colace® 2-IN-1 Tablets

Docusate Sodium

Sennosides

Dist. by: Atlantis Consumer

Healthcare Inc.

LOT XXXXXX

EXP YYYY-MM

#1 DOCTOR RECOMMENDED Stool Softener Brand

Colace®

Docusate Sodium, 50 mg Sennosides 8.6 mg

2-IN-1

Stool Softener + Stimulant Laxative

√ Gentle, Effective, & Dependable

√ Constipation Relief in 6 `12 hours

30Tablets

Retain this carton for Important information

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R52506



Colace®

Docusate Sodium

Sennosides

2-IN-1

Stool Softener + Stimulant Laxative

30Tablets

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R52507



#1 DOCTOR RECOMMENDED Stool Softener Brand

Colace®

Docusate Sodium, 50 mg Sennosides 8.6 mg

2-IN-1

Stool Softener +

Stimulant Laxative

 $\sqrt{}$ Gentle, Effective, & Dependable $\sqrt{}$ Constipation Relief in 6 `12 hours

Retain this carton for Important information For added savings, visit: colacecapsules.com

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R52508 **60**Tablets

A1023

R52507



Colace®

Docusate Sodium Sennosides

2-IN-1

Stool Softener + Stimulant Laxative

60Tablets

Do not use if imprinted seal under cap is missing or damaged.
See carton for additional information

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LOT:

EXP:

A1023

R52509



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
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)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
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)	

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		
4	NDC:67618- 110-12	2 in 1 PACKAGE	01/01/2024	
4		1 in 1 CARTON		
4		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
-		60 in 1 BOTTLE, PLASTIC; Type 0: Not a		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	02/08/1957	

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 4/2025 Atlantis Consumer Healthcare, Inc.