

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

Colace

Drug Facts

| Active ingredient | Purpose |
|--------------------------|--------------------|
| Docusate sodium 50 mg | Stool softener |
| Sennosides 8.6 mg | 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 |
| 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.

Dist. by: Atlantis Consumer Healthcare inc.

Bridgewater, NJ 08801 USA

Questions? 1-833-286-2684

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Consumer Healthcare Inc.

A1023

R52504

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**#1
DOCTOR
RECOMMENDED
Stool Softener Brand**

Colace®

Docosate Sodium, 50 mg

Sennosides 8.6 mg

2-IN-1

**Stool Softener +
Stimulant Laxative**

√ Gentle, Effective, & Dependable

√ Constipation Relief in 6 ` 12 hours

10 Tablets



Colace® 2-IN-1 Tablets

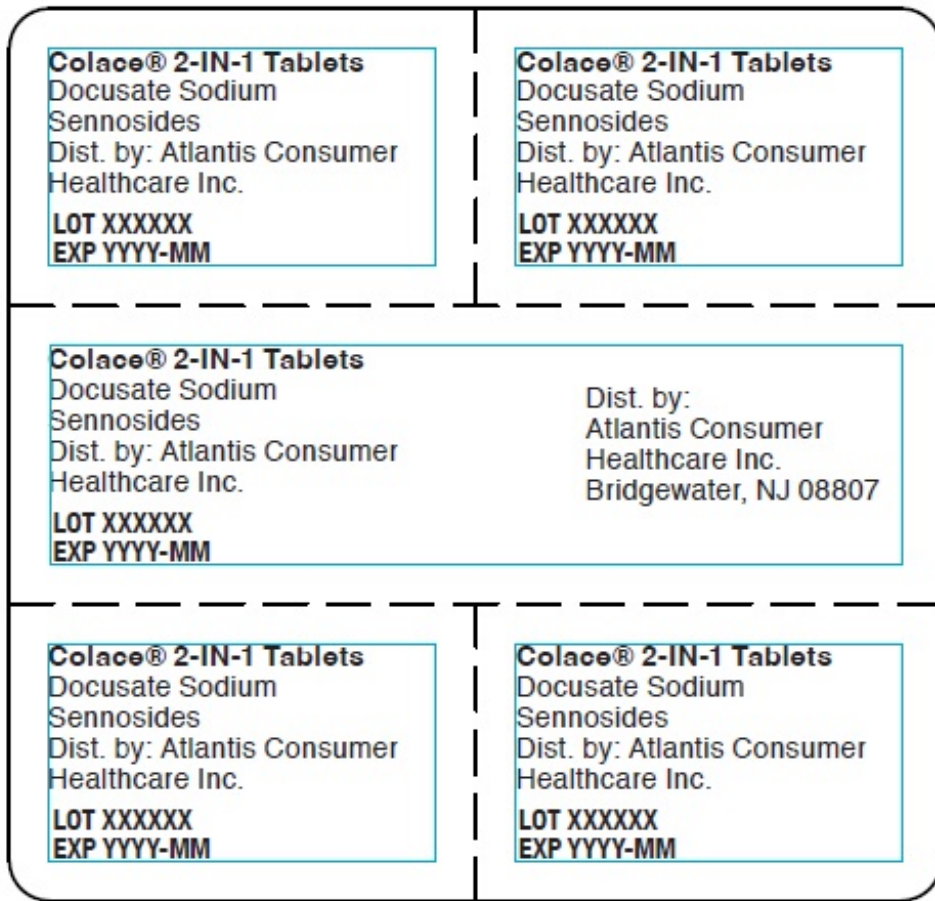
Docusate Sodium

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

30 Tablets

**Retain this carton for
Important information**

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R52506



Colace®

Docosate Sodium

Sennosides

2-IN-1

Stool Softener + Stimulant Laxative

30 Tablets

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

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R52507

Active ingredients (in each tablet):
Docosate sodium 50 mg, Sennosides 8.6 mg

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.

COLACE®
Docosate Sodium
Sennosides

2-IN-1
**Stool Softener +
Stimulant Laxative**

30 Tablets

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

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 by mouth 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** take 1-2 tablets daily; **2 to under 6** take up to 1 tablet daily; **under 2** ask a doctor. Each tablet contains: **calcium 7 mg, sodium 4 mg VERY LOW SODIUM.**

Dist. by: Atlantis Consumer Healthcare Inc.,
Bridgewater, NJ 08807 USA
Questions? 1-833-288-2684
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#1 DOCTOR RECOMMENDED Stool Softener Brand

Colace®

Docosate Sodium, 50 mg
Sennosides 8.6 mg

2-IN-1

Stool Softener +

Stimulant Laxative

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

Retain this carton for Important information

For added savings, visit:

colacecapsules.com

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Questions? 1-833-286-2684

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A1023

R52508
60 Tablets

A1023

R52507



Colace®

Docosate Sodium
Sennosides

2-IN-1

**Stool Softener +
Stimulant Laxative**

60 Tablets

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

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Questions? 1-833-286-2684

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LOT:

EXP:

A1023

R52509

| | | | |
|----------------------------|--|--|--|
| EXP: LOT: R52509 | <p>Active ingredients (in each tablet): Docusate sodium 50 mg, Sennosides 8.6 mg</p> <p>Uses ■ relieves occasional constipation (irregularity) ■ generally produces bowel movement in 6 to 12 hours</p> <p>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</p> <p>Ask a doctor before use if you have ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks</p> <p>Dist. by: Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA Questions? 1-833-288-2684</p> |  <p>COLACE[®] Docusate Sodium Sennosides 2-IN-1 Stool Softener + Stimulant Laxative 60 Tablets</p> <p>Do not use if imprinted seal under cap is missing or damaged. See carton for additional information.</p> | <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions: Take by mouth 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 take 1-2 tablets daily; 2 to under 6 take up to 1 tablet daily; under 2 ask a doctor. Each tablet contains: calcium 7 mg, sodium 4 mg VERY LOW SODIUM. A1023</p> |
|----------------------------|--|--|--|

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 Drug | M007 | 02/08/1957 | |

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 12/2023

Atlantis Consumer Healthcare, Inc.