

STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium and sennosides tablet
Safeway, Inc.

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Stimulant laxative

Uses

- for overnight relief from 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 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 20 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

carnauba wax*, 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, sodium benzoate, stearic acid, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call **1-888-723-3929** Monday-Friday 7AM-6PM PST

Principal Display Panel

COMPARE TO Colace® 2-IN-1 active ingredients†

Stool Softener

Plus Stimulant Laxative

DOCUSATE SODIUM 50 mg

SENNOSIDES 8.6 mg

For overnight relief of occasional constipation

- Gentle
- 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

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PLEASANTON, CA 94566-0009

www.betterlivingbrandsLLC.com

Product Label



Signature Care
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Compare to Colace® 2-IN-1
active ingredients:
NDC 21130-829-20

Stool Softener Plus Stimulant Laxative
DOCUSATE SODIUM 50 mg
SENNOSIDES 8.6 mg

For overnight relief of occasional constipation

- Gentle
- Dependable

Relief in 6-12 hours

Actual Size
200 TABLETS

Drug Facts

Active ingredients (in each tablet)
Stool softener
Docosate sodium 50 mg
Stimulant laxative
Sennosides 8.6 mg

Uses
■ for overnight relief from 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
■ laxative products for relieving mineral oil unless directed by a doctor

Ask a doctor before use if you have
■ stomach pain ■ nausea
■ dizziness ■ vomiting
■ reduced or 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.

Drug Facts (continued under label)

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

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P.O. BOX 99 PLEASANTON, CA 94566-0009
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200393871 (NDC) 3 21130-77889-9 Product of: S2801 RD 18348

PEEL HERE →

Drug Facts (continued)

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.

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| 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 carnuba wax*, croscarmellose sodium, croscic calcium phosphate dihydrate, FD&C blue #2, aluminum lake*, FD&C red #40 aluminum lake, hydroxypropylmethylcellulose, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium benzoate*, stearic acid*, talc*, titanium dioxide

Questions or comments?
Call 1-888-725-3829 Monday-Friday / 7AM-6PM PST

SIGNATURE CARE Stool Softener Plus Stimulant Laxative

STOOL SOFTENER PLUS STIMULANT LAXATIVE

docusate sodium and sennosides tablet

| Product Information | | | |
|---|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-829 |
| 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 |
|--|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSCARMELOSE 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) | |
| 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 | TCL097;PSD21;S44 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:21130-829-20 | 200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M007 | 12/31/2018 | |

Labeler - Safeway, Inc. (009137209)