

STOOL SOFTENER- docusate sodium capsule
Good Sense (Geiss, Destin & Dunn, Inc.)

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 ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Ask a doctor before use if

- stomach pain
- nausea
- vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are

presently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using a laxative. These could be a sign of a serious condition
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health care 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 with a glass of water

| | |
|-----------------------------|--|
| adults and children 12 over | take 1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses. |
|-----------------------------|--|

| | |
|-------------------------------------|----------------------|
| children 2 to under 12 years of age | take 1 softgel daily |
| children under 2 years | ask a doctor |

Other information

- **each softgel contains:** sodium 6 mg
- store 25°C (77°F); excursion permitted between 15-30°C (59-86°F)

Inactive ingredients

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water and sorbitan, sorbitol

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Gentle Stool Softener

Docusate Sodium

Stool Softener Laxative

For Gentle, Softening Relief

Stimulant-Free

†Compare to active ingredient in DulcoEase® Stool Softener

†This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, distributor of DulcoEase®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: Geiss, Destin & Dunn, Inc.

Peachtree City, GA 30269

www.valuelabels.com

Product Label

GOODSENSE®

NDC 50804-584-25

Gentle Stool Softener

For Gentle, Softening Relief

Docosate Sodium Stool Softener Laxative

Actual Size



Stimulant-free

25 Softgels (100 mg Each)

*Compare to active ingredient in DulcoEase® Stool Softener

100% SATISFACTION GUARANTEED

Gentle Stool Softener

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING. KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: Geiss, Deslin & Dunn, Inc.
Peachtree City, GA 30269
www.valuelabels.com



PLD-0101
FC004461

Lot No.:

Exp. Date:

This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of DulcoEase®.

Drug Facts (continued)

Other information: sodium 6 mg

inactive ingredients: edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Drug Facts

Active ingredient (in each softgel): Docosate sodium 100 mg

Purpose: Stool softener laxative

Uses: for temporary relief of occasional constipation and irregularity; this product generally produces bowel movement in 12 to 72 hours

Warnings: Ask a doctor before use if you have stomach pain, nausea, vomiting, a sudden change in bowel habits that lasts more than 2 weeks, or you are presently taking mineral oil.

Stop use and ask a doctor if: you have rectal bleeding or no bowel movement after using 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 with a glass of water

| | |
|---------------------------------------|--|
| adults and children 12 years and over | take 1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses. |
| children 2 to under 12 years of age | take 1 softgel daily |
| children under 2 years | ask a doctor |

GOOD SENSE Gentle Stool Softener

STOOL SOFTENER

docosate sodium capsule

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50804-584 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM | 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0K00R) | |
| SORBITOL (UNII: 506T60A25R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

Product Characteristics

| | | | |
|----------|--------|--------------|-------------|
| Color | ORANGE | Score | no score |
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | P51;SCU1;D2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50804-584-25 | 1 in 1 BOX | 08/31/2018 | |
| 1 | | 25 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 | 08/31/2018 | |

Labeler - Good Sense (Geiss, Destin & Dunn, Inc.) (076059836)

Revised: 12/2019

Good Sense (Geiss, Destin & Dunn, Inc.)