

STOOL SOFTENER- docusate calcium capsule, liquid filled

CVS Pharmacy

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 calcium 240 mg

Purpose

Stool softener laxative

Uses

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

Warnings

Do not use

if you are currently 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 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.
- you need to use a laxative for more than 1 week

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

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59°-86°F)

Inactive ingredients

corn oil, D&C red #33*, edible white ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6*, gelatin, glycerin, purified water, sorbitol special

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in Surfak®†

Stool Softener

DOCUSATE CALCIUM, 240 mg

Stool Softener Laxative

Sodium Free

- Gentle Relief of Constipation
- Once-a-day dosage

SOFTGELS

†This product is not manufactured or distributed by Chattem, Inc., distributor of Surfak®.

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

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One CVS Drive, Woonsocket, RI 02895

Product Label

CVS Health. Compare to the active ingredient in Surfak®
NDC 59779-134-10

Stool Softener

DOCUSATE CALCIUM, 240 mg
Stool Softener Laxative

Sodium Free

- Gentle relief of constipation
- Once-a-day dosage



Actual Size

100 SOFTGELS

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Drug Facts (continued under label)
#139598

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One CVS Drive
Woodstock, NJ 02815
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Member Since 1963

PLD-A2069 Lot No.: 0 5042842489 6
L3056914 Exp. Date:

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CVS HEALTH Stool Softener Laxative

| STOOL SOFTENER | | | |
|--|----------------|--------------------|---------------|
| docusate calcium capsule, liquid filled | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-134 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| DOCUSATE CALCIUM (UNII: 6K7YS503HC) (DOCUSATE - UNII:M7P27195AG) | | DOCUSATE CALCIUM | 240 mg |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| CORN OIL (UNII: 8470G57WFM) | | | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | | |
| GELATIN (UNII: 2G86QN327L) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |

| | |
|------------------------------------|--|
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | RED | Score | no score |
| Shape | CAPSULE | Size | 18mm |
| Flavor | | Imprint Code | P58;SCU |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59779-134-01 | 1 in 1 BOX | 04/30/2014 | |
| 1 | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:59779-134-10 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/30/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part334 | 04/30/2014 | |

Labeler - CVS Pharmacy (062312574)