

STOOL SOFTENER LAXATIVE- docusate sodium capsule EQUALINE (SuperValu)

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 occasional constipation and irregularity
- this product generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently 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 last 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 a 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

- 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 |

Other information

- **each softgel contains:** sodium 5 mg
- store at 25°C (77°F); excursions 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 sorbitan, sorbitol

Questions or comments?

Call toll free **1-855-423-2630**

Principal Display Panel

compare to Dulcolax® Stool Softener active ingredient†

stool softener

docusate sodium 100 mg

stool softener laxative

- comfortable relief of painful, hard, dry stool
- stimulant-free
- constipation relief

Softgels

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

PROVIDENCE, RI 02908 USA

Product Label

Exp. Date:

Lot No.:

FC006778

PLD-66718

0 4 1 1 6 3 4 5 8 2 7 7



EQUALINE®

compare to Dulcolax® Stool Softener active ingredient! NDC 41163-862-25

stool softener

docusate sodium 100mg stool softener laxative

- comfortable relief of painful, hard, dry stools
- stimulant-free
- constipation relief



actual size

25 softgels

DISTRIBUTED BY UNFI PROVIDENCE, RI 02908 USA

Like it or let us make it right. That's our quality promise. 855-423-2630



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Drug Facts (continued)

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Directions ■ take with a glass of water

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
 ■ 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.
 ■ 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.

Uses
 ■ for relief of occasional constipation and irregularly
 ■ this product generally produces bowel movement in 12 to 72 hours

Active ingredient (in each softgel)
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Purpose

EQUALINE Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-862 |
| 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: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | P51 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:41163-862-25 | 1 in 1 BOX | 01/31/2020 | |
| 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 | 01/31/2020 | |

Labeler - EQUALINE (SuperValu) (006961411)