

STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled 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 USP, 100 mg

Purpose

Stool softener laxative

Uses

- for relief of 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 told to do so by a doctor.

Ask a doctor before use if

- 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 using a laxative. These could be a sign of a serious condition.
- you need to use a stool softener 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 (1-800-222-1222) right away.

Directions

- take with a glass of water

| | |
|---------------------------------------|--|
| adults and children 12 years and over | take 1-3 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 7 mg
- store at 25°C (77°F); excursion permitted between 15-30°C (59-86°F)

Inactive ingredients

citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special, white edible ink

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 stools
- stimulant-free
- Relief of occasional constipation

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

Lot No.:
Exp. Date:

PRODUCT OF CHINA

0 41163 45827 7

PLD-H790A F0008393

EQUALINE[®]

compare to Dulcolax[®] Stool Softener
active ingredient*
NDC 41163-107-25

stool softener

docusate sodium 100mg
stool softener laxative

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

25 softgels

actual size 

DISTRIBUTED BY UNFI
PROVIDENCE, RI 02908 USA

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

100% Quality GUARANTEED

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Drug Facts

Active ingredient (in each softgel)
Docusate sodium USP, 100 mgStool softener laxative

Uses

- for relief of occasional constipation and irregularly
- 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
- 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 (1-800-222-1222) right away.

Directions ■ take with a glass of water

| | |
|------------------------|--|
| adults and children | 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 | take 1 softgel daily |
| children under 2 years | ask a doctor |

Drug Facts (continued)

Other information

- each softgel contains: sodium 7 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients citric acid, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special, white edible ink

Questions or comments?
 Call toll free 1-855-423-2630

*This product is not manufactured or distributed by Chatham, Inc., distributor of Dulcolax[®] Stool Softener.

EQUALINE Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-107(NDC:53345-008) |
| 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) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SORBITAN (UNII: 6O92ICV9RU) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | red | Score | no score |
| Shape | CAPSULE | Size | 13mm |
| Flavor | | Imprint Code | PC1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41163-107-25 | 1 in 1 BOX | 12/30/2022 | |
| 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

12/30/2022

Labeler - EQUALINE (SuperValu) (006961411)

Revised: 1/2023

EQUALINE (SuperValu)