

TOPCARE STOOL SOFTENER- docusate sodium capsule, liquid filled
TOPCO ASSOCIATES LLC

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.

Docusate Sodium 100 mg..... Stool Softener

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener

Uses

- relieves occasional constipation (irregularity)
- generally produces a 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 you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel movements 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 stool softener 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 only by mouth. Doses may be taken as a single daily dose or in divided doses.

| | |
|---------------------------------------|----------------------------|
| adults and children 12 years and over | take 1 to 3 softgels daily |
| children 2 to under 12 years of age | take 1 softgel daily |
| children under 2 years | ask a doctor |

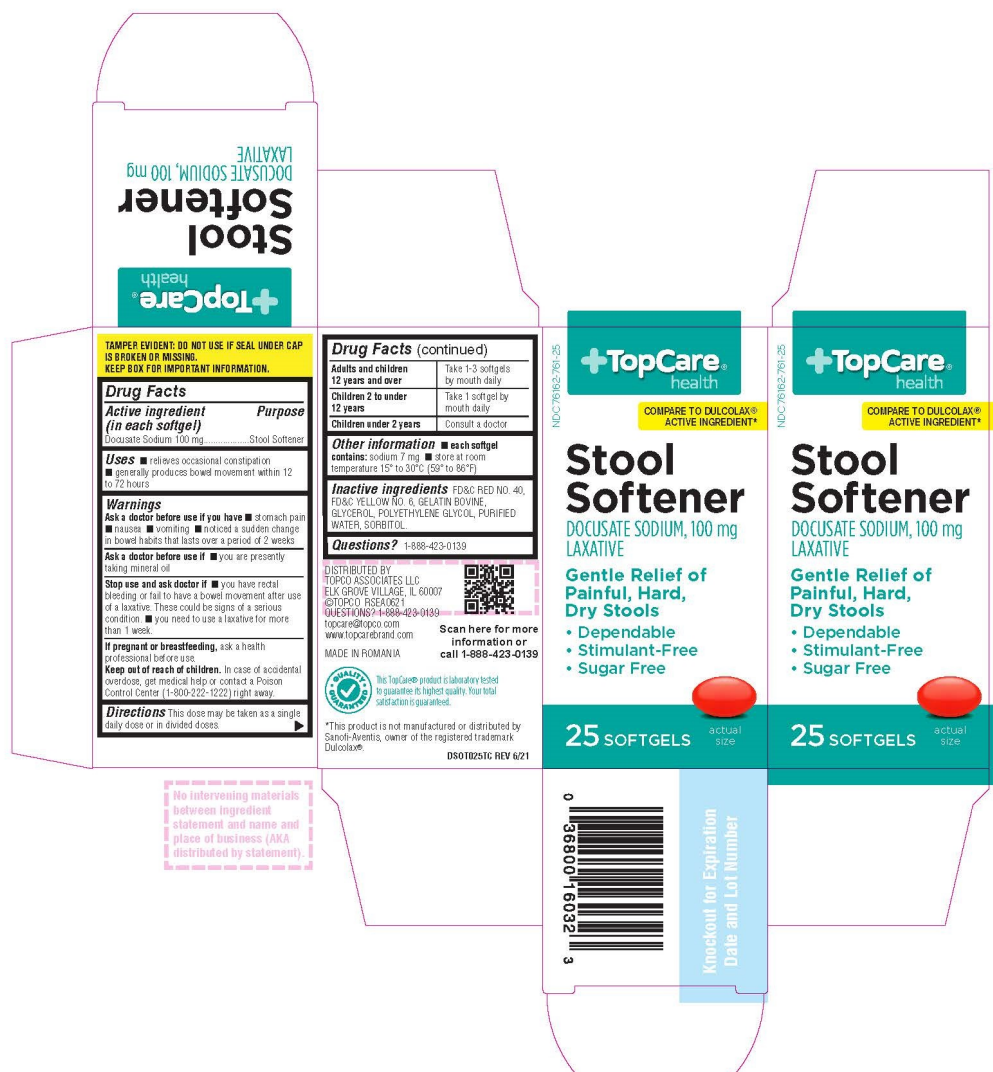
Other information

- each softgel contains: sodium 7 mg
- store at room temperature 15° to 30°C (59° to 86°F)

Inactive Ingredients

FD&C RED NO. 40, FD&C YELLOW NO. 6, GELATIN BOVINE, GLYCEROL, POLYETHYLENE GLYCOL, PURIFIED WATER, SORBITOL.

Display Panel



DISTRIBUTED BY
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TOPCARE STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76162-761 |
| 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) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|----------|
| Color | red | Score | no score |
| Shape | CAPSULE (OVAL) | Size | 12mm |
| Flavor | | Imprint Code | SCU1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76162-761-25 | 1 in 1 CARTON | 07/20/2021 | |
| 1 | | 25 in 1 BOTTLE; 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 | 07/20/2021 | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 12/2022

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