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 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- 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 you have

- stomach pain
- nausea
- vomiting
- 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 (1-800-222-1222) 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 1-3 softgels dailychildren 2 to under 12 years of agetake 1 softgel dailychildren under 2 yearsask 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

ammonium hydroxide, anhydrous citric acid, D&C red #33, ethyl alcohol, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, n-butyl alcohol, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call toll free 1-855-423-2630

Principal Display Panel

compare to Colace® Regular Strength Stool Softener active ingredient†

Stool Softener

docusate sodium 100 mg

Stool softener laxative

relieves constipation

softgels

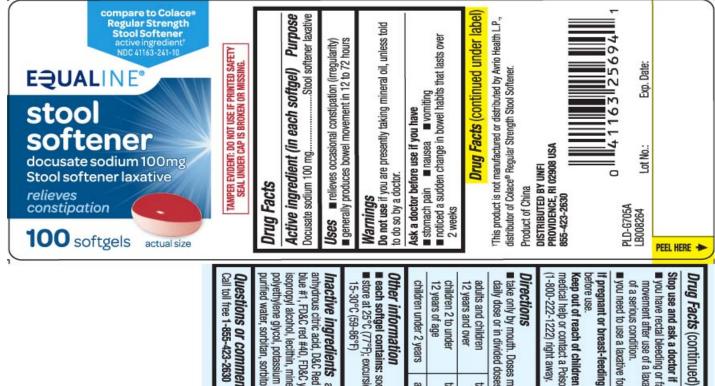
†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

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

DISTRIBUTEDBY UNFI

PROVIDENCE, RI 02908 USA

Product Label



| actal bleeding or a lax after use of a lax s condition. | 1 ask a doctor if ectal bleeding or fail to have a bowel after use of a laxative. These could be signs s condition. b use a laxative for more than 1 week |
|---|--|
| r breast-feedin reach of childrer or contact a Pois 222) right away | vr breast-feeding, ask a health professional reach of children. In case of overdose, get or contact a Poison Control Center (222) right away. |
| S y mouth. Doses ma or in divided doses. | S y mouth. Doses may be taken as a single or in divided doses. |
| children 1d over | take 1-3 softgels daily |
| to under Fage | take 1 softgel daily |
| der 2 years | ask a doctor |
| ormation gel contains: °C (77°F); excu 19-86°F) | ormation ger contains: sodium 5 mg °C (77°F); excursions permitted between 19-86°F) |
| ngredients tric acid, D&C R C red #40, FD&C bhol, lecithin, mi glycol, potassiu glycol, potassiu | ingredients ammonium hydroxide, rric acid, D&C Red #33, ethyl alcohol, FD&C C red #40, FD&C yellow # 6, gelatin, glycerin, bhol, lecithin, mineral oil, n-butyl alcohol, glycol, potassium hydroxide, propylene glycol, r, sorbitan, sorbitol, titanium dioxide |
| s or comments? 1-855-423-2630 | ents? |

EQUALINE Stool Softener Laxative

| STOOL SOFTENER L | ΑΧΑΤΙνε | | | | |
|-------------------------------|----------------------------|---------------|-------------|---------|----------|
| docusate sodium capsule, lic | luid filled | | | | |
| Product Information | | | | | |
| Product Type | HUMAN OTC DRUG | ltem Code (So | urce) | NDC:411 | 63-241 |
| Route of Administration | ORAL | | | | |
| | | | | | |
| Active Ingredient/Active | Moiety | | | | |
| Ingr | edient Name | | Basis of St | rength | Strength |
| DOCUSATE SODIUM (UNII: F05Q2 | 2T2JA0) (DOCUSATE - UNII:M | 7P27195AG) | DOCUSATE SO | DIUM | 100 mg |
| | | | | | |
| Inactive Ingredients | | | | | |
| | Ingredient Name | | | S | trength |
| D&C RED NO. 33 (UNII: 9DBA0SB | BOL) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K | 3TBD) | | | | |
| FD&C RED NO. 40 (UNII: WZB912 | 27XOA) | | | | |
| FD&C YELLOW NO. 6 (UNII: H77' | VEI93A8) | | | | |

| GELATIN (UNII: 2G86QN327L) | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITAN (UNII: 6092ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| AMMONIA (UNII: 5138Q19F1X) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| BUTYL ALCOHOL (UNII: 8PJ61P6TS3) | |
| POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| | |

Product Characteristics

| Color | red, white | Score | no score |
|----------|------------|--------------|----------|
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | PC18 |
| Contains | | | |

Packaging

| 1NDC:41163- 241-20200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product03/26/20212NDC:41163- 241-10100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product03/26/2021 | # | ltem Code | Package Description | Marketing Start Date | Marketing End Date |
|--|---|----------------------|---------------------|-------------------------|-----------------------|
| | 1 | NDC:41163- 241-20 | | 03/26/2021 | |
| | | | | 03/26/2021 | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|----------------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| OTC monograph not final | part334 | 03/26/2021 | |

Labeler - EQUALINE (SuperValu) (006961411)

Revised: 11/2022

EQUALINE (SuperValu)