STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled Major Pharmaceuticals

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 250 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- this product generally produces a bowel movement within 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 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

 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

- each softgel contains: sodium 13 mg
- store between 20-25°C(68-77°F); excursions permitted between 15-30°C (59-86°F)

Inactive Ingredients

anhydrous citric acid, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mannitol, mineral oil, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions?

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

Principal Display Panel

Extra Strength

Docusate Sodium

250 mg

Stool Softener Laxative

Softgels

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

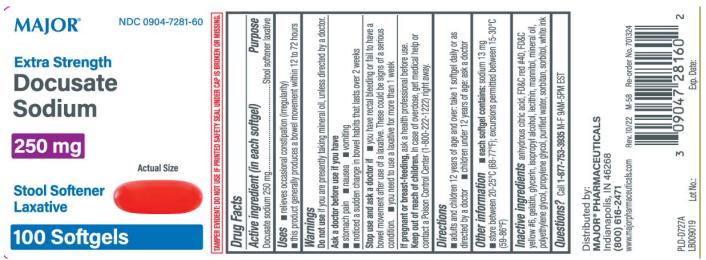
Distributed by:

MAJOR PHARMACEUTICALS

Indianapolis, IN 46268

www.majorpharmaceuticals.com

Product Label



MAJOR Extra Strength Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0904-7281 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|---|--------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM | 250 mg | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| MANNITOL (UNII: 30WL53L36A) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| SORBITAN (UNII: 6092ICV9RU) | |
| | |

Product Characteristics

| Color | orange (Clear) | Score | no score |
|----------|----------------|--------------|----------|
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | P4 |
| Contains | | | |

| l | Packaging | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:0904- 7281-80 | 1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/14/2022 | |

2 NDC:0904-7281-60 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 10/14/2022

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M007 | 10/14/2022 | | |

Labeler - Major Pharmaceuticals (191427277)

Revised: 4/2024 Major Pharmaceuticals