DOCUSATE SODIUM- docusate sodium capsule A-S Medication Solutions

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
- 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 (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 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 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 **1-800-616-2471**

HOW SUPPLIED

Product: 50090-6140

NDC: 50090-6140-1 100 CAPSULE in a BOTTLE, PLASTIC

DOCUSATE SODIUM



DOCUSATE SODIUM

docusate sodium capsule

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-6140(NDC:0904-6998)

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, UNSPECIFIED (UNII: 2G86QN327L) | | | | | |
| SORBITAN (UNII: 6092ICV9RU) | | | | | |
| 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 | | | | | |

| l | Packaging | | | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|--|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| | 1 | NDC:50090- 6140-1 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/03/2022 | | | |

| Marketing Information | | | | | | |
|---|------|------------|--|--|--|--|
| Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date | | | | | | |
| OTC Monograph Drug | M007 | 02/28/2020 | | | | |
| | | | | | | |

Labeler - A-S Medication Solutions (830016429)

| Establishment | | | | | | |
|--------------------------|---------|-----------|----------------------------|--|--|--|
| Na me | Address | ID/FEI | Business Operations | | | |
| A-S Medication Solutions | | 830016429 | RELABEL(50090-6140) | | | |

Revised: 11/2023 A-S Medication Solutions