

DOK- docusate sodium capsule
A-S Medication Solutions

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
- 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 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 6 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

*contains one or more of these ingredients

Questions or comments?

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

HOW SUPPLIED

Product: 50090-5268

NDC: 50090-5268-0 20 CAPSULE in a BOTTLE

NDC: 50090-5268-1 100 CAPSULE in a BOTTLE

NDC: 50090-5268-2 60 CAPSULE in a BOTTLE

DOK (DOCUSATE SODIUM) CAPSULE



DOK

docusate sodium capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-5268(NDC:0904-6457) |
| 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, UNSPECIFIED (UNII: 2G86QN327L) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|-----------------|
| Color | ORANGE | Score | no score |
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | P51;S77;SCU1;D2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50090-5268-0 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 10/19/2020 | |
| 2 | NDC:50090-5268-2 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 10/19/2020 | |
| 3 | NDC:50090-5268-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/19/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

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|-------------------------|---------|------------|--|
| OTC MONOGRAPH NOT FINAL | part334 | 02/28/2015 | |
|-------------------------|---------|------------|--|

Labeler - A-S Medication Solutions (830016429)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| A-S Medication Solutions | | 830016429 | RELABEL(50090-5268) , REPACK(50090-5268) |

Revised: 3/2021

A-S Medication Solutions