**DOCUSATE SODIUM- docusate sodium liquid**
**Major Pharmaceuticals**

*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.*

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**Docusate Sodium**

***Drug Facts***

**Active ingredient (in each 5 mL)**

Docusate sodium 50 mg

**Purpose**

Stool softener

**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 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
- rash occurs

**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**

- Dose once daily
- take with 6 to 8 oz of milk, juice or infant formula to mask the bitter taste.

| | |
|---|---|
| adults and children 12 years and older | 5 to 20 mL (1 to 4 teaspoonfuls) |
| children 6 to under 12 years of age | 5 to 10 mL (1 to 2 teaspoonfuls) |
| children 3 to under 6 years of age | 2.5 to 5 mL (1/2 to 1 teaspoonful) |
| children under 3 years | ask a doctor |

**Other information**

- • Sodium content: 14 mg/ 5 mL
  • Store at controlled room temperature, 20° to 25°C (68° to 77°F)
  • Protect from freezing
  • Protect from light
  • Clear pink to purple-pink colored, cherry flavored liquid supplied in the following:

NDC 0904-7279-66: 10 mL unit dose cup, in a tray of ten cups.

**Inactive ingredients**

artificial cherry vanilla flavoring, citric acid anhydrous, D&C Red No. 33, glycerin, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, saccharin sodium, sodium citrate, and sorbitol.

**Questions or comments?**

Call 1-800-845-8210

R06/22

**Distributed by:**

**MAJOR ® PHARMACEUTICALS**

Indianapolis, IN 46268

**PRINCIPAL DISPLAY PANEL - 10 mL Cup Tray Label**

**NDC 0904-7279-66**

**Docusate Sodium Liquid**

**100 mg/10 mL**

**STOOL SOFTENER LAXATIVE**

Alcohol Free/Sugar Free

**Delivers 10 mL**

**See insert**

**For Institutional Use Only**

MAJOR ® PHARMACEUTICALS

Indianapolis, IN 46268

**F0935C100622**


# DOCUSATE SODIUM

docusate sodium liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-7279 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DOCUSATE SODIUM** (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM | 50 mg in 5 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **D&C RED NO. 33** (UNII: 9DBA0SBB0L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SORBITOL SOLUTION** (UNII: 8KW3E207O2) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | pink (Clear pink to purple-pink) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | CHERRY (Cherry-Vanilla) | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0904-7279-72 | 10 in 1 CASE | 12/05/2022 | |
| **1** | | 10 in 1 TRAY | | |
| **1** | NDC:0904-7279-66 | 10 mL in 1 CUP, UNIT-DOSE; 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 | 08/16/2021 | |

## Labeler - Major Pharmaceuticals (191427277)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Pharmaceutical Associates, Inc. | | 097630693 | manufacture(0904-7279, 0904-7279) |