

## **DOCUSATE SODIUM- docusate sodium liquid**

### **Major Pharmaceuticals**

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#### **Docusate Sodium**

#### **Active Ingredient**

(in each 5 mL)  
Docusate sodium 100 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.

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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

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**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 colored, cherry-vanilla 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

**Distributed by:**

R06/22

MAJOR® PHARMACEUTICALS  
Indianapolis, IN 46268

**Principal Display Panel**

MAJOR

NDC 0904-7279-66  
Docusate Sodium Liquid

100 mg/10 mL  
Stool Softener Laxative

F0935C100622



## DOCUSATE SODIUM

docusate sodium liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7279
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)	
<b>RED 33</b> (UNII: 9DBA0SBB0L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	pink (Clear pink to purple pink)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Cherry-Vanilla)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7279-72	10 in 1 CASE	12/08/2022	
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 Drug	M007	12/08/2022	

**Labeler** - Major Pharmaceuticals (191427277)