

## **DOCUSATE SODIUM- docusate sodium capsule, liquid filled**

### **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.*

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## **Perrigo Docusate Sodium 100 mg 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 lasts over 2 weeks

#### **Ask a doctor or pharmacist before use if you are**

taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

#### **When using this product**

do not exceed the maximum recommended daily dosage in a 24-hour period

#### **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 right away. (1-800-222-1222)

**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 - 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
- very low sodium
- store at 20-25°C (68-77°F)

**Inactive ingredients**

D&C red no. 33, edible ink, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

**Questions?**

1-800-719-9260

**DOCUSATE SODIUM CAPSULE, LIQUID FILLED**



## DOCUSATE SODIUM

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-5524(NDC:45802-486)
<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

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	RED, WHITE (to off beige)	<b>Score</b>	no score
<b>Shape</b>	OVAL (softgel)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	L486
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5524-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/28/2008	

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5524)

Revised: 4/2021

A-S Medication Solutions