

**DOCUSATE SODIUM- docusate sodium capsule, liquid filled**  
**Northwind 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 100mg**

**Active ingredient (in each softgel)**

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

**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
	take 1 softgel

children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

### Other information

- **Tamper Evident: do not use if safety seal under cap is broken or missing**
- each capsule contains: **sodium 6 mg**
- **VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15 °-30 °C (59 °-86 °F).

Keep tightly closed.

### This Package for Households Without Young Children

### Inactive ingredients

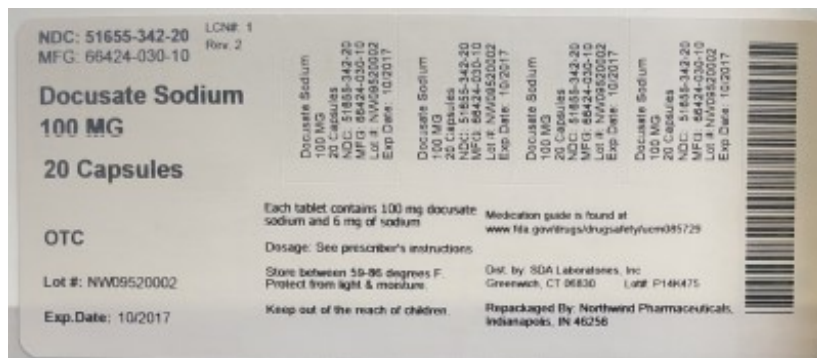
D&C Red #33, Edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, titanium dioxide

### Questions?

**Adverse drug event call: (800) 722-0772 Mon- Fri 8 AM to 5 PM**

\* This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®.

### Package Label.Principal Display



NDC: 51655-342-20

MFG: 66424-399-10

Docusate Sodium 100 MG

20 Capsules

OTC

Lot#:

Exp. Date:

Each tablet contains 100 mg docusate sodium and 6 mg of sodium

Dosage: See prescriber's instructions

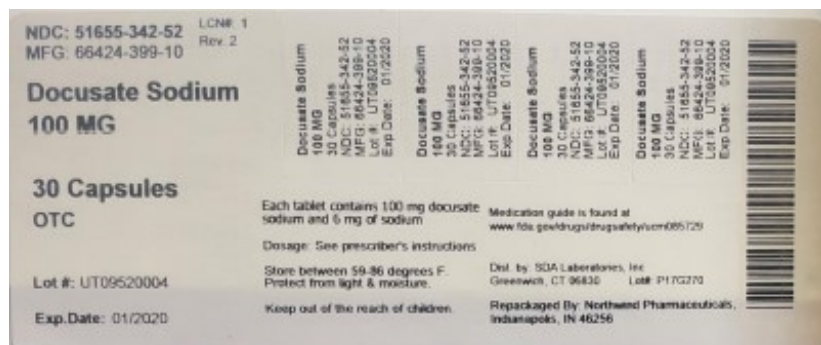
Store between 59-86 degrees F. Protect from light & moisture.

Keep out of the reach of children.

Medication guide is found at [www.fda.gov/drugs/drugsafety/ucm085729](http://www.fda.gov/drugs/drugsafety/ucm085729)

Dist. by: SDA Laboratories, Inc Greenwich, CT 06830 Lot#:

Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256



NDC: 51655-342-52

MFG: 66424-399-10

Docusate Sodium 100 MG

30 Capsules

OTC

Lot#:

Exp. Date:

Each tablet contains 100 mg docusate sodium and 6 mg of sodium

Dosage: See prescriber's instructions

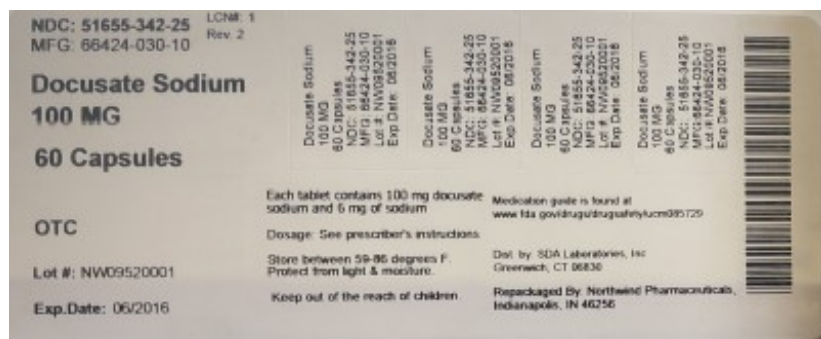
Store between 59-86 degrees F. Protect from light & moisture.

Keep out of the reach of children.

Medication guide is found at [www.fda.gov/drugs/drugsafety/ucm085729](http://www.fda.gov/drugs/drugsafety/ucm085729)

Dist. by: SDA Laboratories, Inc Greenwich, CT 06830 Lot#:

Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256



NDC: 51655-342-25

MFG: 66424-030-10

Docusate Sodium 100 MG

60 Capsules

OTC

Lot#:

Exp. Date:

Each tablet contains 100 mg docusate sodium and 6 mg of sodium

Dosage: See prescriber's instructions

Store between 59-86 degrees F. Protect from light & moisture.

Keep out of the reach of children.

Medication guide is found at [www.fda.gov/drugs/drugsafety/ucm085729](http://www.fda.gov/drugs/drugsafety/ucm085729)

Dist. by: SDA Laboratories, Inc Greenwich, CT 06830 Lot#:

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## DOCUSATE SODIUM

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51655-342(NDC:66424-399)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	red (Two toned- white and clear red)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	SCU2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-342-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2017	
2	NDC:51655-342-52	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/14/2017	

**Labeler** - Northwind Pharmaceuticals (036986393)

**Registrant** - Northwind Pharmaceuticals (036986393)

## Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-342)

Revised: 3/2015

Northwind Pharmaceuticals