STOOL SOFTNER- docusate sodium capsule, liquid filled
Unit Dose Services

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

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 15º-30ºC (59º-86ºF).

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) 687-0176 Mon- Fri 8 AM to 4 PM

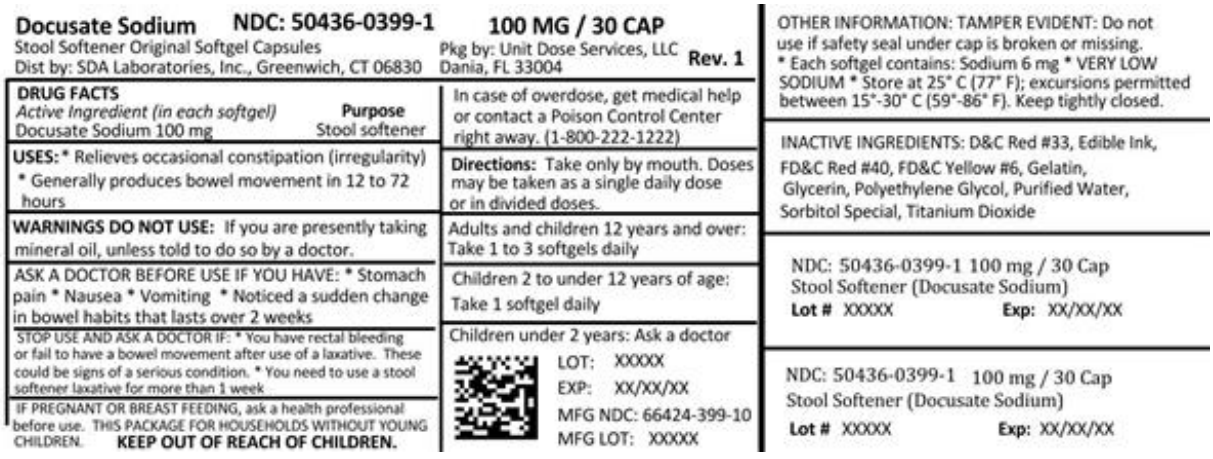
* This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®.

HOW SUPPLIED

Product: 50436-0399

NDC: 50436-0399-1 30 CAPSULE, LIQUID FILLED in a BOTTLE

STOOL SOFTNER (DOCUSATE SODIUM) CAPSULE, LIQUID FILLED



STOOL SOFTNER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-0399(NDC:66424-399)
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-0399-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/01/2016	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0399) , RELABEL(50436-0399)

Revised: 8/2017 Unit Dose Services