DOCUSATE SODIUM - docusate sodium liquid
Physicians Total Care, Inc.

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 teaspoon)

Docusate Sodium 50 mg

Purpose

Stool Softener Laxative

Uses

- relieves occasional constipation
- generally produces bowel movement in 12-72 hours

Warnings

Do not use

- if you are presently taking mineral oil
- when abdominal pain, nausea, or vomiting are present
- for longer than one week

Ask a doctor before use if you have

noticed a sudden change in bowel habits that lasts over two 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.

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use of this product

These may indicate a serious condition.

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

- may be taken once daily or in divided doses
- give dose in 1/2 glass of milk, fruit juice or infant formula to mask bitter taste and prevent throat irritation
-

adults and children over 12	1 to 7 teaspoons
children 2 to under 12	1 to 3 teaspoons
children under 2	ask a doctor

Other information

- **each teaspoon contains:** sodium 5 mg
- shake well before using
- store at controlled room temperature 15° - 30°C (59° - 86°F)
- dispense contents with a child resistant closure in a tight, light resistant container as defined in the USP.

Inactive ingredients

D&C Red #33, methylparaben, planifoline, poloxamer 181, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium benzoate. Sodium citrate may be used to adjust pH.

Questions or comments?

- Call **1-800-262-9010**
  Mon. - Thurs. 9:00 am - 4:30 pm EST,
  Fri. 9:00 am - 2:30 pm EST.
  Serious side effects associated with use of this product may be reported to this number.

REV. 771:04 07/10

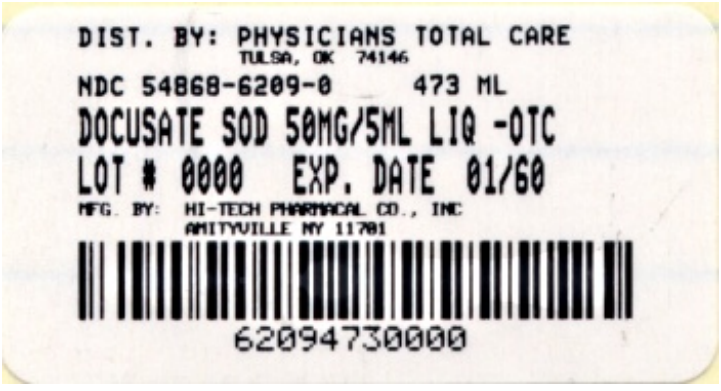
PRINCIPAL DISPLAY PANEL

DOCU LIQUID

(Docusate Sodium 50 mg/5 mL)

NDC 54868-6209-0

NET CONTENTS ONE PINT (473 mL)



STOOL SOFTENER LAXATIVE

TAMPER EVIDENT: FOR YOUR PROTECTION, THIS BOTTLE HAS A SAFETY SEAL AROUND THE NECK OR UNDER THE CAP.

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Additional bar code labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

DOCUSATE SODIUM

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-6209(NDC:50383-771)
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**
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
VANILLA (UNII: Q74T35078H)	
WATER (UNII: 059QF0KO0R)	
POLOXAMER 181 (UNII: 09Y8E6164A)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6209-0	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/07/2010	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 1/2012 Physicians Total Care, Inc.