DOCU LIQUID- docusate sodium liquid
Akorn Operating Company LLC

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

Docusate Sodium 50 mg

Purpose

Stool Softener Laxative

Keep Out of Reach of Children

Uses

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

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
- **store in an upright position**

Inactive Ingredients

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

Questions or comments?

- **Call 1-800-932-5676**

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.

Package/Label Principal Display Panel

NDC 50383-771-16

DOCU LIQUID

(Docusate Sodium 50 mg/5 mL)

STOOL SOFTENER LAXATIVE

TAMPER EVIDENT: FOR YOUR PROTECTION THE CHILD RESISTANT CAP HAS A PRINTED SAFETY SEAL AROUND THE NECK. DO NOT ACCEPT IF BROKEN OR MISSING.

Distributed by:

Akorn Operating Company LLC

Gurnee, IL 60031

NET CONTENTS ONE PINT (473 mL)

Package/Label Principal Display Panel

Delivers 10 mL

NDC 50383-349-10

DOCU LIQUID

(DOCUSATE SODIUM)

100 mg/ 10 mL

STOOL SOFTENER LAXATIVE

SEE INSERT

Barcode 3 5038334910 5

FOR INSTITUTIONAL USE ONLY

Distributed by:

Akorn Operating Company LLC

Gurnee, IL 60031

Rev. 349:01 04/22

DOCU LIQUID

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
POLOXAMER 181 (UNII: 09Y8E6164A)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor	VANILLA (natural and artificial flavor)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50383-771-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/01/1997	

DOCU LIQUID

docusate sodium liquid

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Active Ingredient/Active Moiety

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Product Characteristics

Color	PINK	**Score**	
Shape		**Size**	
Flavor	VANILLA (natural and artificial flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-349-11	10 in 1 CASE	05/28/2021	
1		10 in 1 TRAY		
1	NDC:50383-349-10	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 not final	part334	08/01/1997	

Labeler - Akorn Operating Company LLC (117696873)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations

Akorn Operating Company LLC		117696873	MANUFACTURE(50383-771, 50383-349) , PACK(50383-771, 50383-349)