DOCUSATE SODIUM- docusate sodium liquid liquid
Pharmaceutical Associates, 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.

Docusate Sodium

Drug Facts

Active ingredient (in each 5 mL)

Docusate sodium 50 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
- rash occurs

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

- Dose once daily
- take with 6 to 8 oz of milk, juice or infant formula to mask the bitter taste.

adults and children 12 years and older	5 to 20 mL (1 to 4 teaspoonfuls)
children 6 to under 12 years of age	5 to 10 mL (1 to 2 teaspoonfuls)
children 3 to under 6 years of age	2.5 to 5 mL (1/2 to 1 teaspoonful)
children under 3 years	ask a doctor

Other information

- • Sodium content: 14 mg/ 5 mL
  • Store at controlled room temperature, 20° to 25°C (68° to 77°F)
  • Protect from freezing
  • Protect from light
  • Clear pink to purple-pink colored, cherry flavored liquid supplied in the following:

NDC 0121-0935-16: 16 fl oz (473 mL) bottle
NDC 0121-0935-05: 5 mL unit dose cup, in a tray of ten cups.
NDC 0121-1870-10: 10 mL unit dose cup, in a tray of ten cups.

Inactive ingredients

artificial cherry vanilla flavoring, citric acid anhydrous, D&C Red No. 33, glycerin, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, saccharin sodium, sodium citrate, and sorbitol.

Questions or comments?

Call 1-800-845-8210

MANUFACTURED BY

Pharmaceutical Associates, Inc.

Greenville, SC 29605

R12/20

PRINCIPAL DISPLAY PANEL - 16 fl oz (473 mL)

NDC 0121-0935-16

Docusate Sodium Liquid

50 mg/5 mL

STOOL SOFTENER LAXATIVE

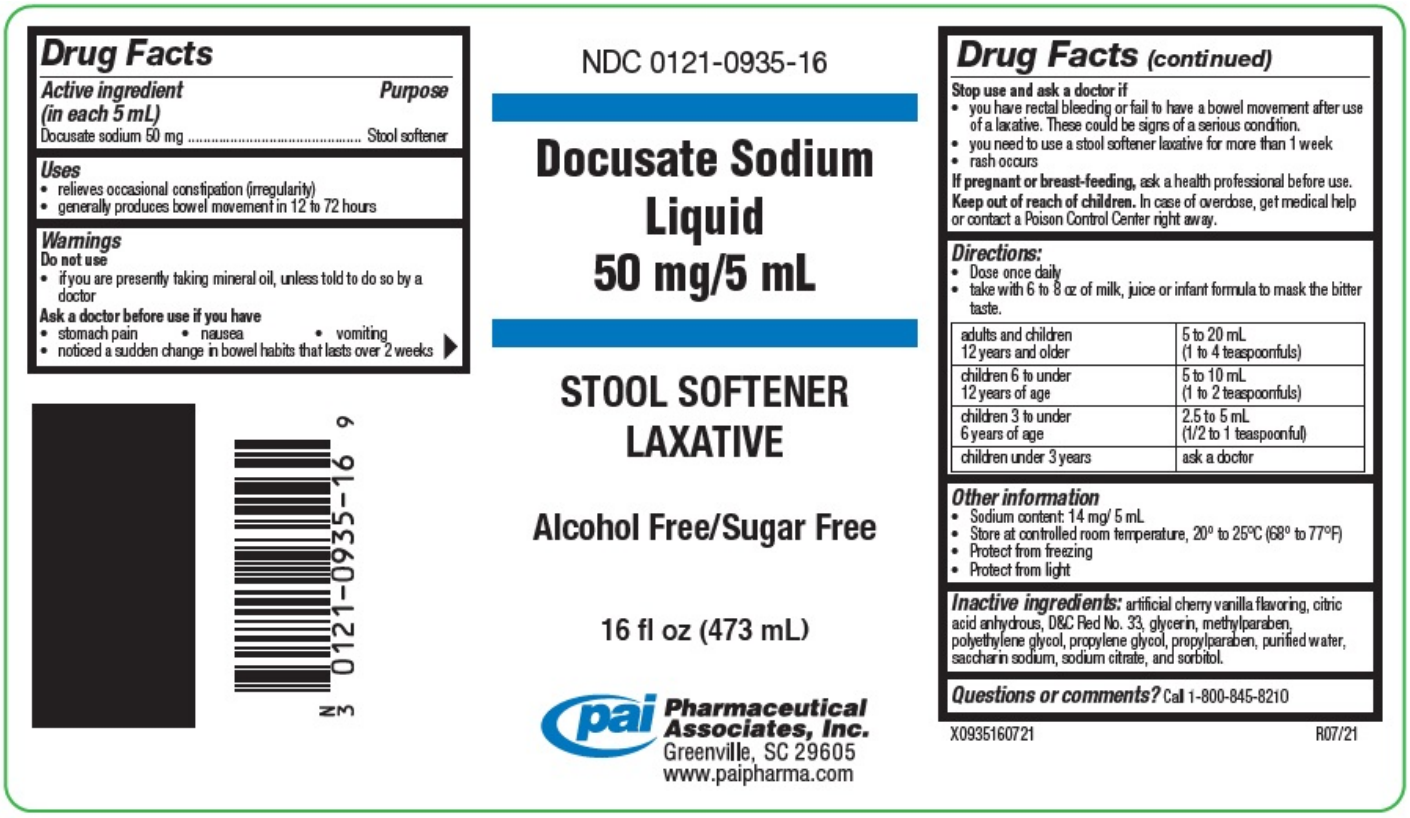
Alcohol Free/Sugar Free

16 fl oz (473 mL)

Pharmaceutical Associates, Inc.

Greenville, SC 29605

X0935160721 R07/21



PRINCIPAL DISPLAY PANEL - 5 mL Cup Tray Label

NDC 0121-0935-05

Docusate Sodium Liquid

50 mg/5 mL

STOOL SOFTENER LAXATIVE

Alcohol Free/Sugar Free

Package Not Child-Reistant

Pharmaceutical Associates, Inc.

Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 10 mL Cup Tray Label

NDC 0121-1870-10

Docusate Sodium Liquid

100 mg/10 mL

STOOL SOFTENER LAXATIVE

Alcohol Free/Sugar Free

Package Not Child-Reistant

Pharmaceutical Associates, Inc.

Greenville, SC 29605

DOCUSATE SODIUM

docusate sodium liquid liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0935

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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	pink (Clear pink to purple-pink)	**Score**	
Shape		**Size**	
Flavor	CHERRY (Cherry-Vanilla)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0935-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2021	
2	NDC:0121-0935-40	4 in 1 CASE	08/16/2021	
2		10 in 1 TRAY		
2	NDC:0121-0935-05	5 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	08/16/2021	

DOCUSATE SODIUM

docusate sodium liquid liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1870
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 in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	purple (Clear pink to purple-pink)	**Score**	
Shape		**Size**	
Flavor	CHERRY (Cherry-Vanilla)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1870-00	10 in 1 CASE	08/16/2021	
1		10 in 1 TRAY		
1	NDC:0121-1870-10	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	08/16/2021	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0935, 0121-1870)

Revised: 9/2021 Pharmaceutical Associates, Inc.