

DOCUSATE SODIUM- docusate sodium liquid
PAI Holdings, LLC dba PAI Pharma

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

Drug Facts Active ingredient (in each 5 mL) Docusate sodium 50 mg Stool softener Purpose Stool softener Uses <ul style="list-style-type: none">relieves occasional constipation (irregularity)generally produces bowel movement in 12 to 72 hours Warnings Do not use <ul style="list-style-type: none">if you are presently taking mineral oil, unless told to do so by a doctor Ask a doctor before use if you have <ul style="list-style-type: none">stomach painnauseavomitingnoticed a sudden change in bowel habits that lasts over 2 weeks	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 www.paipharma.com	Drug Facts (continued) Stop use and ask a doctor if <ul style="list-style-type: none">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 weekrash 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: <ul style="list-style-type: none">Dose once dailytake with 6 to 8 oz of milk, juice or infant formula to mask the bitter taste. <table border="1"><tr><td>adults and children 12 years and older</td><td>5 to 20 mL (1 to 4 teaspoonfuls)</td></tr><tr><td>children 6 to under 12 years of age</td><td>5 to 10 mL (1 to 2 teaspoonfuls)</td></tr><tr><td>children 3 to under 6 years of age</td><td>2.5 to 5 mL (1/2 to 1 teaspoonful)</td></tr><tr><td>children under 3 years</td><td>ask a doctor</td></tr></table> Other information <ul style="list-style-type: none">Sodium content: 14 mg/ 5 mLStore at controlled room temperature, 20° to 25°C (68° to 77°F)Protect from freezingProtect from light 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	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
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X0935160721 R07/21

PRINCIPAL DISPLAY PANEL - 5 mL Cup Lidding

NDC 0121-0935-05

Docusate Sodium Liquid

50 mg/5 mL

STOOL SOFTENER LAXATIVE

Alcohol Free/Sugar Free

Package Not Child-Resistant

Pharmaceutical Associates, Inc.

Greenville, SC 29605



PRINCIPAL DISPLAY PANEL - 10 mL Cup Lidding

NDC 0121-1870-10

Docusate Sodium Liquid

100 mg/10 mL

STOOL SOFTENER LAXATIVE

Alcohol Free/Sugar Free

Package Not Child-Resistant

Pharmaceutical Associates, Inc.

Greenville, SC 29605



DOCUSATE SODIUM

docusate sodium 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	10/31/2025
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 Drug	M007	08/16/2021	

DOCUSATE SODIUM

docusate sodium 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
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OTC Monograph Drug	M007	08/16/2021	
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Labeler - PAI Holdings, LLC dba PAI Pharma (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	analysis(0121-0935, 0121-1870) , label(0121-0935, 0121-1870) , manufacture(0121-0935, 0121-1870)

Revised: 2/2025

PAI Holdings, LLC dba PAI Pharma