

DOCUSATE SODIUM- docusate sodium liquid
Safecor Health, LLC

SAFECOR HEALTH
Docusate Sodium Liquid
Drug Facts

Active Ingredient (in each 5 mL = 1 teaspoonful)

Docusate Sodium 50 mg

Purpose

Stool Softener

Use:

Relief of occasional constipation

WARNINGS:

Do not use * when abdominal pain, nausea, or vomiting are present * for a period longer than 1 week unless directed by a doctor

Ask a doctor before use if you * have noticed a sudden change in bowel habits that persist over a period of 2 weeks * are taking mineral oil

Stop use and ask a doctor if you have rectal bleeding or failure to have a bowel movement within 3 days.

These could be signs of a serious condition. * a skin rash occurs * you experience throat irritation

If pregnant or breast feeding, ask a health care professional before use.

Keep this and all drugs out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately. In case of eye contact, flush with water.

Directions:

- * Must be given in a 6 oz to 8 oz glass of milk or fruit juice to prevent throat irritation
- * Shake well before using
- * Do not exceed recommended dose
- * May be taken in one to four equally divided oral doses each day
- * Take maximum dose daily until first bowel movement, dosage should then be reduced according to individual response

Adults and children 12 years of age and over	5 mL (1 teaspoon) to 40 mL (8 teaspoons) or as directed by a doctor
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Children 6 to 12 years of age	4 mL to 15 mL (3 teaspoons) or as directed by a doctor
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Children 3 to 6 years of age	2 mL to 6 mL or as directed by a doctor
Children under 3 years of age	1 mL to 4 mL or as directed by a doctor

1 teaspoon = 5 mL

Other information: Each teaspoon (5 mL) contains: sodium 5 mg. Store at room temperature 20°C-25°C (68°F-77°F); excursions between 15°C-30°C (59°F-86°F) are allowed. Protect from excessive heat. Protect from light. For more info call 1-800-447-1006.

Inactive ingredients: FD&C red #40, flavor, methylparaben, poloxamer, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium benzoate, sodium citrate, and sucralose.

NDC: 48433-220-10 Docusate Sodium Liquid 100 mg/10 mL Unit Dose Cup

Mfd. in the U.S.A.

Distributed by: Safecor Health, LLC

4060 Business Park Drive, Columbus, OH 43204

11/2020 PN5473

3 4843322010 8

Rev:

Principal Display Panel - Box Label

SAFECOR

HEALTH

Docusate Sodium Liquid

100 mg / 10 ml

Contains 40 (10 ml) Unit Dose Cups

See monograph for complete drug information.

NDC: 48433-220-40

QTY: 40

Lot: 21A0079

Exp: 2023-03-31

Store at room temperature 20°C-25°C (68°F-77°F); excursions between 15°C-30°C (59°F-86°F) are allowed.

Protect from excessive heat. Protect from light.

This package design is not child resistant. For institutional use only.

Shake well before use.

3 48433 22040 5

Pkg By: Safecor Health, LLC Columbus, OH 43204

Questions or Comments: Call 1-800-447-1006

GTIN: 00348433220405

SN: 212802331

Exp; 2023-03-31

Lot 21A0079 PN5689.C

SAFECOR
HEALTH

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100 mg / 10 mL

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See monograph for complete drug information.

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3 48433 22040 5

Pkg By: Safecor Health, LLC Columbus, OH 43204
Questions or Comments: Call 1-800-447-1006



GTIN: 00348433220405
SN: 212802331
Exp: 2023-03-31
Lot: 21A0079

PN5689.C

SAFECOR
HEALTH

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100 mg / 10 mL

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3 48433 22040 5

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Questions or Comments: Call 1-800-447-1006



GTIN: 00348433220405
SN: 212802331
Exp: 2023-03-31
Lot: 21A0079

Principal Display Panel - Lid Label

Delivers **10 mL**

NDC 48433-220-10

Docusate

Sodium Liquid

100 mg/10mL

SHAKE WELL

348433220108

Pkg By: Safecor Health, LLC

Columbus, OH 43204

PN5618.B



DOCUSATE SODIUM

docusate sodium liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-220(NDC:54859-813)
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-220-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	09/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M334	09/01/2021	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(48433-220)

Revised: 1/2025

Safecor Health, LLC