DOCUSATE SODIUM- docusate sodium liquid
Safecor Health, 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.

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
Children 6 to 12 years of age	4 mL to 15 mL (3 teaspoons) or as directed by a doctor
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 Rev: 11/2020 PN5473

3 4843322010 8

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

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: 3WQ0SDW1A)	
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 not final	part334	09/01/2021	

Labeler - Safecor Health, LLC (828269675)

Establishment

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

Revised: 1/2023 Safecor Health, LLC