

STOOL SOFTENER SYRUP- docusate sodium syrup
AMERISOURCEBERGEN DRUG CORPORATION

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.

GNP DOCUSATE SYRUP

Active ingredient (in each 15 mL tablespoonful)

Docusate Sodium 60 mg

Purpose

Stool Softener Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use for more than one week unless directed by a doctor

Ask a doctor before use if you

- have abdominal pain, nausea, or vomiting
- are taking mineral oil
- have noticed a sudden change in bowel habits that lasts more than 14 days
- have a sodium-restricted diet

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 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

- follow dosing directions below or take as directed by doctor
- must be given in a 6 to 8 oz glass of milk or fruit juice to prevent throat irritation
- may be taken as a single daily dose or in divided doses
- take maximum daily dose until first bowel movement, then reduce dose according to individual response
- shake well before using

Adults and children 12 years and over	1 to 3 tablespoonfuls (15 to 45 mL)
Children under 12 years of age	ask a doctor

Other information

- **Each 15 mL tablespoonful contains:** sodium 51 mg
- Store at room temperature 15°- 30° C (59°-86° F)
- protect from excessive heat
- Keep tightly closed

Inactive ingredients

citric acid, D&C Red #33, FD&C Red #40, flavors, glycerin, propylene glycol, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water.

package label

NDC 46122-400-43

Compare to Colace® Syrup active ingredient *

GOOD NEIGHBOR PHARMACY

STOOL

SOFTENER

SYRUP

Docusate Sodium

Relieves Constipation

60 mg/15 mL

16 FL OZ (473 mL)

NDC 46122-400-43

Compare to Colace® Syrup active ingredient*



STOOL SOFTENER SYRUP

Docusate Sodium

Relieves Constipation

60 mg/15 mL
16 FL OZ (473 mL)

Drug Facts

Tamper Evident: Do not use if breakaway band on cap is broken or missing.

Active ingredient (in each 15 mL tablespoonful)	Purpose
Docusate Sodium 60 mg.....	Stool Softener Laxative

Uses • relieves occasional constipation (irregularity)
• generally produces bowel movement in 12 to 72 hours

Warnings

Do not use for more than one week unless directed by a doctor

Ask a doctor before use if you • have abdominal pain, nausea, or vomiting
• are taking mineral oil • have noticed a sudden change in bowel habits that lasts more than 14 days • have a sodium-restricted diet

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 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 • follow dosing directions below or use as directed by a doctor
• must be given in a 6 oz to 8 oz glass of milk or fruit juice to prevent throat irritation • may be taken as a single daily dose or in divided doses
• take maximum daily dose until first bowel movement, then reduce dose according to individual response • shake well before using

Adults and children 12 years and over	1 to 3 tablespoonfuls (15 to 45 mL)
Children under 12 years of age	ask a doctor

Other information • Each 15 mL tablespoonful contains: sodium 51 mg
• Store at room temperature 15°-30° C (59°-86° F) • protect from excessive heat
• Keep tightly closed

Inactive ingredients citric acid, D&C Red #33, FD&C Red #40, flavors, glycerin, propylene glycol, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water.

Questions or comments? 1-800-540-3765

*This product is not manufactured or distributed by the owner of the registered trademark Colace® Syrup.

Distributed By
AmerisourceBergen
1300 Morris Drive
Chesterbrook, PA 19087
Questions or Concerns?
www.mygnp.com



STOOL SOFTENER SYRUP

docusate sodium syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-400
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	60 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-400-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2017	09/30/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/01/2017	09/30/2020

Labeler - AMERISOURCEBERGEN DRUG CORPORATION (007914906)**Registrant** - GERI-CARE PHARMACEUTICAL CORP (611196254)

Revised: 12/2019

AMERISOURCEBERGEN DRUG CORPORATION