

STOOL SOFTENER- docusate sodium capsule, liquid filled
Allegiant Health

424-Stool Softener- Single Tone

Active ingredient(s)

Docusate sodium 100mg

Purpose

Stool softener

Use(s)

- 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

- stomach pain
- nausea
- vomiting
- notice a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.
- you need a laxative for more than 1 week

Pregnancy/Breastfeeding

ask a health professional before use.

Keep out of reach of children

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Take only by mouth.

Adults and children 12 years and over: take 1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses.

Children 2 to under 12 years of age: take 1 softgel daily

Children under 2 years of age: ask a doctor

Other information

- each softgel contains: sodium 5mg
- VERY LOW SODIUM
- do not use if imprinted safety seal under cap is broken or missing

Storage

Store at room temperature 15°-30°C (59°-86°F), protect from excessive humidity.

Inactive ingredients

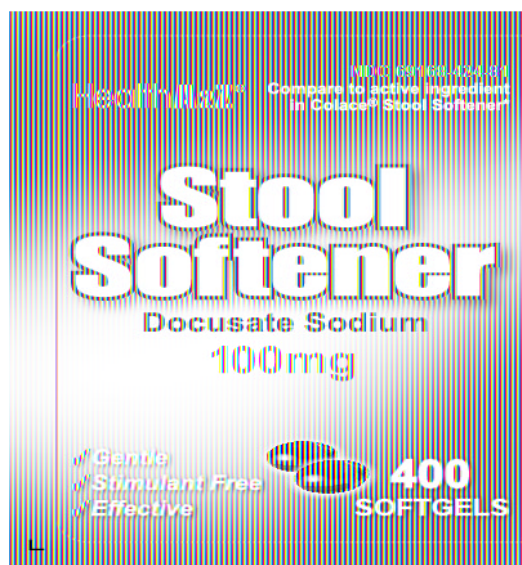
Anhydrous citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol,

propylene glycol, purified water, sorbitol sorbitan solution and white edible ink.

Questions

Call 1-888-952-0050 Monday to Friday 9am-5pm

Principal Display Panel



Stool Softener

Drug Facts	Purpose Docosate sodium 100mg..... Stool softener
Active ingredient (in each softgel) Docosate sodium 100mg	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 vomiting or 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. If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
Directions Take only by mouth. Adults and children 12 years and over: take 1-3 softgels daily. Doses may be taken as a single daily dose or in divided doses. Children 2 to under 12 years of age: take 1 softgel daily Children under 2 years: ask a doctor	Other information each softgel contains sodium 5mg very low sodium store at room temperature 15°-30° C (59°-86° F), protect from excessive humidity do not use if imprinted safety seal under cap is broken or missing
Inactive ingredients Anhydrous citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution and white edible ink.	

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-424
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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	PC1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-424-81	400 in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2021	
2	NDC:69168-424-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/28/2015	

