STOOL SOFTENER- docusate sodium capsule
Allegiant Health

420-Stool Softener

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

you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over a period of 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

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 1-3 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
- do not use if imprinted safety seal under cap is broken or missing.

Storage

- store at 25°C (77°F) excursions permitted between 15°– 30°C (59°–86°F)

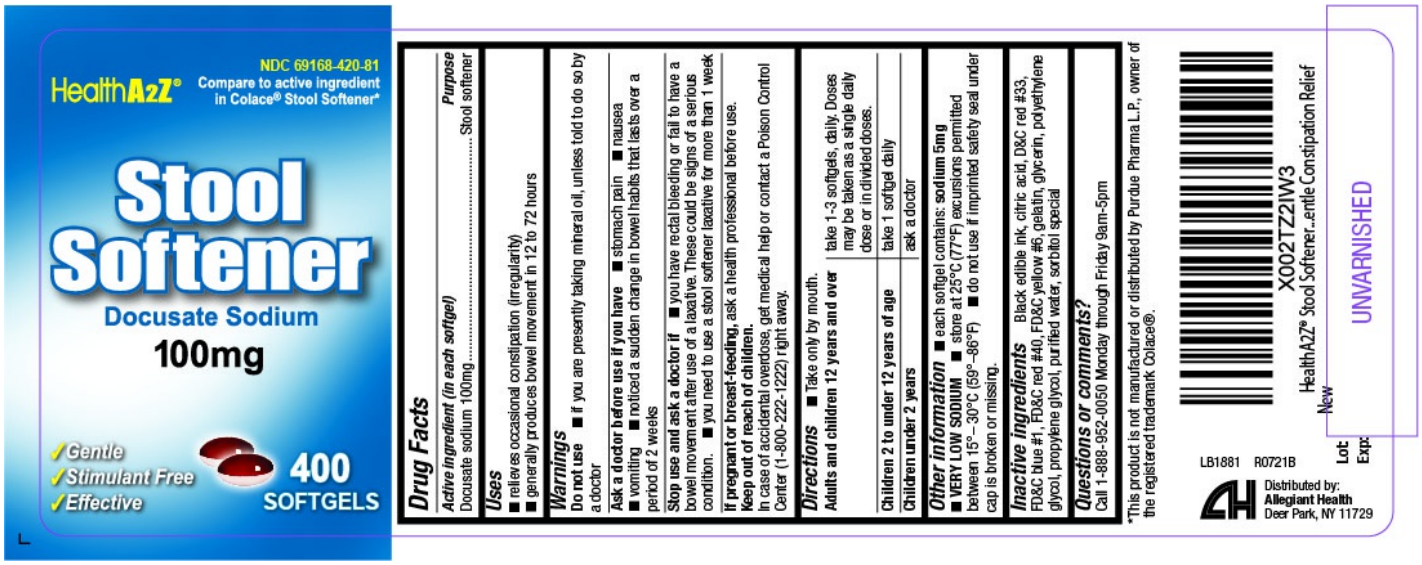
Inactive ingredients

black edible ink, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special

Questions

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

Principal Display Panel



Stool Softener

STOOL SOFTENER

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-420
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red, white	**Score**	no score
Shape	CAPSULE	**Size**	13mm
Flavor		**Imprint Code**	PC18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-420-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2015	
2	NDC:69168-420-81	400 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2021	
3	NDC:69168-420-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	04/10/2015	

Labeler - Allegiant Health (079501930)

Revised: 10/2020 Allegiant Health