STOOL SOFTENER- docusate sodium 100 mg capsule, liquid filled
GERITREX 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.

DOCUSATE SODIUM

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

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

- stomach pain
- nausea
- vomitting
- notice 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 bowel movement after use of laxative. These could be signs of serious condition.
- you need to use a laxative for more than 1 week

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 right away

Directions

take only by mouth. Doses may be taken as a single daily does or in divided doses.

Adults and children 12 years and over	take 1-3 softgels daily

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 6 mg
- store at 25°C (77°F); excursions premitted between 15-30°C (59-86°F)

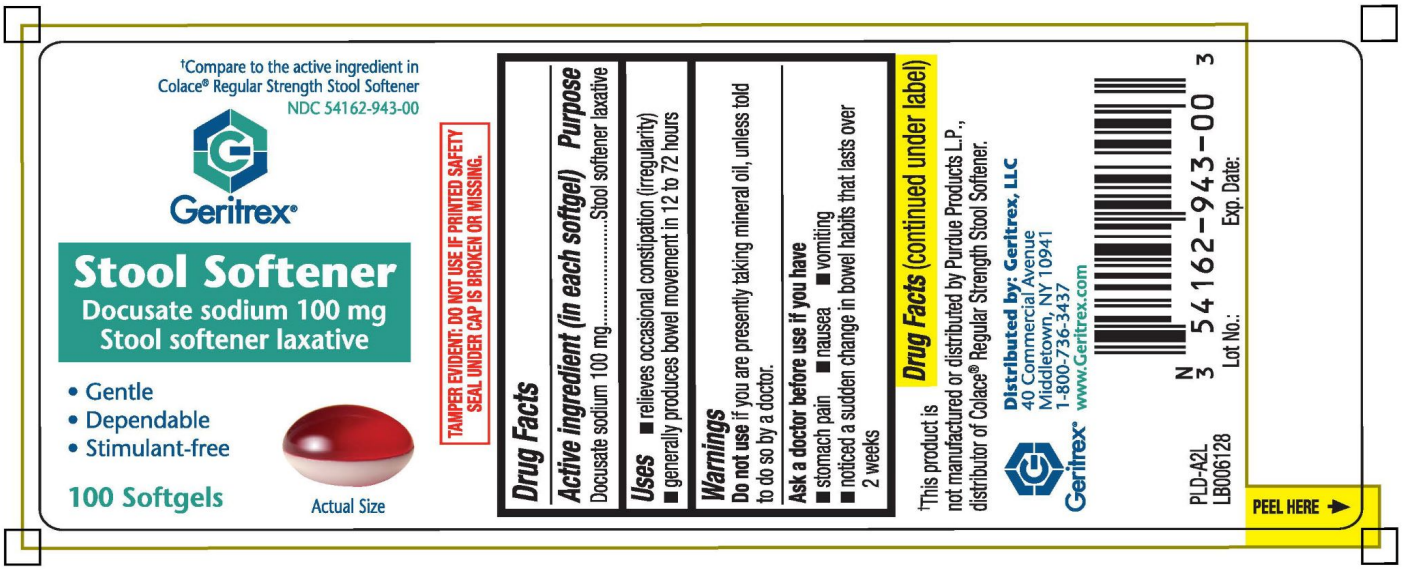
Inactive ingredients

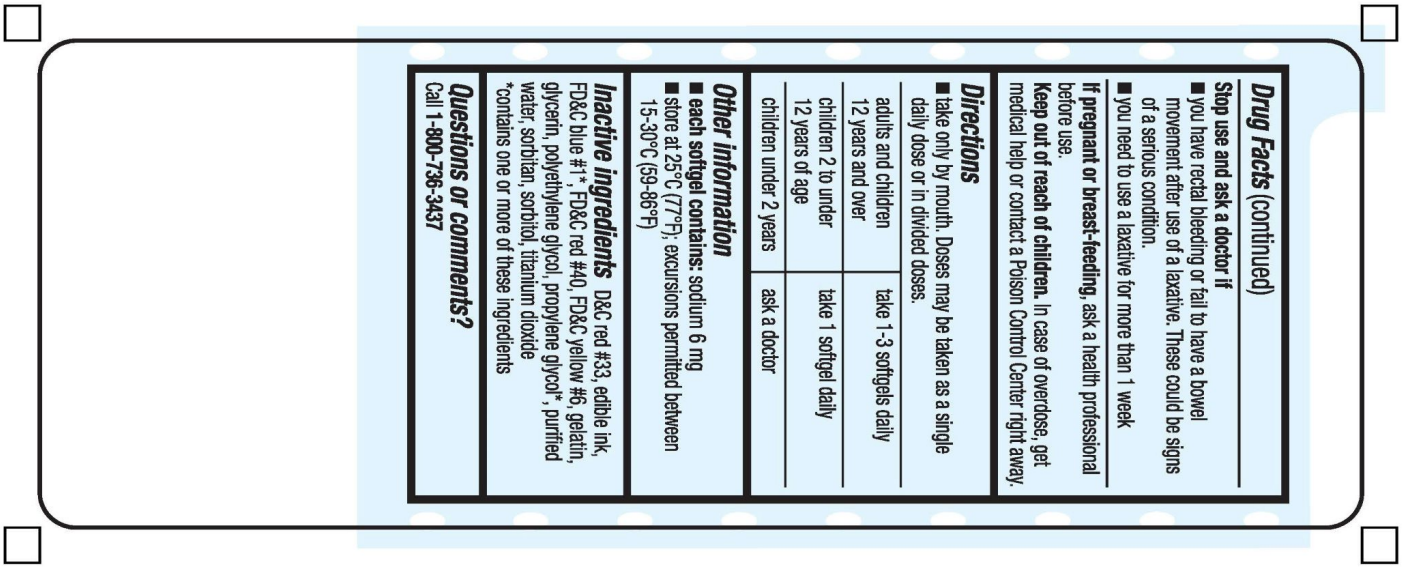
D&C red #33, editable ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide
*contains one or more of these ingredients.

Questions or comments?

Call 1-800-736-3437

Label





STOOL SOFTENER

docusate sodium 100 mg capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-943
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
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)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red, white	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	D1;P10;SCU2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-943-00	100 in 1 BOX; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/01/2018	

Labeler - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-943)

Revised: 9/2018 GERITREX LLC