

**GENTLE RELIEF STOOL SOFTNER- gentle relief stool softnet capsule, gelatin coated
Healthlife of USA**

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.

Gentle Relief Stool Softner

Drug Facts

Gentle Relief Stool Softner

Purpose

Stool Softner

Active Ingredient (in each softgel)

Docusate sodium 100mg

Uses

- For prevention of dry, hard stools
- For relief of occasional constipation.

This product generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

- If you are presently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- For 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 continues over a period of 2 weeks

Stop use and ask a doctor if

- You have rectal bleeding
- you fail to have a bowel movement after use

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children

Overdose warning: In case of overdosage, get medical help or contact a Poison Control Center right away.

Directions

- Take with a glass of water
- Adults and children 12 years of age and over: Take 1 to 3 softgels daily. This dose may be taken as 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: Consult a physician

Other Information

Each softgel contains sodium 6 mg

Store at controlled room temperature 15°-30°C (59°-86°F)

Read all product information before using

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING**

Inactive ingredients

- FD&C Red # 40
- FD&C Yellow # 6
- Gelatin
- Glycerin
- Polyethylene glycol 400
- Propylene glycol
- Purified water
- Sorbitol solution
- Titanium dioxide

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST or www.healthlifeofusa.com

Gentle Relief**Stool Softner****Docosate Sodium 100mg****Gentle and Easy Relief of Constipation****24 Softgels****Distributed by:**

Healthlife of USA LLC

Rahway

NJ 07065

www.healthlifeofusa.com

Compare to Dulcolax® Stool Softner active ingredients



GENTLE RELIEF STOOL SOFTNER

gentle relief stool softnet capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-124
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	red	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-124-24	1 in 1 CARTON	05/31/2017	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/31/2017	

Labeler - Healthlife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Healthlife of USA		079656178	repack(69517-124)

Establishment

Name	Address	ID/FEI	Business Operations
Softech Pharma Pvt. Ltd.		677111277	manufacture(69517-124) , pack(69517-124)