

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

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**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 overdose, 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](http://www.healthlifeofusa.com)

## **Gentle Relief**

### **Stool Softner**

### **Docusate Sodium 100mg**

### **Gentle and Easy Relief of Constipation**

### **24 Softgels**

## **Distributed by:**

**Healthlife of USA LLC**

**Rahway**

**NJ 07065**



## GENTLE RELIEF STOOL SOFTNER

gentle relief stool softnet capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69517-124
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KOOR)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**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 Drug	M007	05/31/2017	

**Labeler** - Healthlife of USA (079656178)**Establishment**

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

