

**SENNOSIDES- sennosides capsule, liquid filled  
SOFTGEL HEALTHCARE PRIVATE LIMITED**

*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.*

-----  
**Sennosides 17.2 mg Softgels (Senna)**

**Active ingredient**

(in each softgel)  
Sennosides 17.2 mg

**Purpose**

Laxative

**Uses**

- relieves occasional constipation (irregularity)
- generally produces a bowel movement within 6-12 hours

**Do not use**

- laxative products for longer than 1 week unless directed by a doctor

**Ask a doctor before use if you have**

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that continues over a period of 2 weeks

**Stop use and consult a doctor if**

you have rectal bleeding or fail to have a bowel movement after use of a laxative. These may indicate a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children**

In case of overdose, get medical help or contact a Poison Control Center right away

**Directions**

- take preferably at bedtime or as directed by a doctor adults and children 12 years and over
- 1 capsule once a day. Maximum 2 capsules twice a day. children 6 to under 12 years
- maximum 1 capsule twice a day children under 6 years
- ask a doctor

**Other Information**

store below 30°C (86°F) and protect from light and moisture

**Inactive ingredients**

FD&C blue no.1, FD&C blue no.2, FD&C red no. 40, FD&C yellow no.6, fumaric acid, gelatin, glycerol, lecithin, liquid sorbitol, methyl hydroxy benzoate, purified water, refined soya oil, titanium dioxide, yellow bees wax.

**Questions or comments?**

call 1-877-770-3183: weekdays 9:00 AM to 4:30 PM EST

## SENNOSIDES

sennosides capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0423
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	17.2 mg

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FUMARIC ACID (UNII: 88XHZ13131)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	

### Product Characteristics

<b>Color</b>	brown (Maroon coloured, opaque soft gelatin capsules containing dark brown coloured oily mass)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0423-1	1000 in 1 BAG; Type 0: Not a Combination Product	05/29/2019	
2	NDC:35916-0423-2	2000 in 1 BOX; Type 0: Not a Combination Product	05/29/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/29/2019	

**Labeler** - SOFTGEL HEALTHCARE PRIVATE LIMITED (675584180)

### Establishment

Name	Address	ID/FEI	Business Operations
SOFTGEL HEALTHCARE PRIVATE LIMITED		675584180	manufacture(35916-0423)

Revised: 1/2023

SOFTGEL HEALTHCARE PRIVATE LIMITED