

**SENNOSIDES- sennosides capsule, liquid filled
Granules USA Inc**

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.

**EXTRA STRENGTH
Senna Softgels
Standardized Senna Concentrate
Sennosides 17.2 mg**

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 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.

Package Label Principal Display Panel



SENNOSIDES

sennosides capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

WATER (UNII: 059QF0KO0R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SOYBEAN OIL (UNII: 241ATL177A)	
FUMARIC ACID (UNII: 88XHZ13131)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-016-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/29/2020	

Labeler - Granules USA Inc (137098864)

Revised: 3/2023

Granules USA Inc