LEADER SENNA LAXATIVE - sennosides tablet Cardinal Health

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.

Leader Senna Laxative

Active Ingredients (in each tablet)

Sennosides 8.6mg

Purpose

Stool softener Stimulant Laxative

Uses

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

Warnings - Do not use

• laxative products for longer than 1 week unless told to do so by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel movements 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. These could be signs of a serious condition

If pregnant or breastfeeding

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

age; starting dosage; maximum dosage

- **adults and children 12 years of age:** 2 tablets once a day; 4 tablets twice a day.
- **children 6 to under 12 years of age:** 1 tablet once a day; 2 tablets twice a day
- **children 2 to under 6 years of age:** 1/2 tablet once a day; 1 tablet twice a day
- **children under 2**: ask a doctor; ask a doctor

Other information

- each tablet contains: calcium 25mg/tablet
- store at 25C (77F); excursions permitted between 15 30 degrees C (59-86 degrees F)
- do not use if imprinted safety seal under cap is broken or missing.
- *This product is not manufactured or distributed by Purdue Products, LP, owner of the registered trademark Senokot.

Inactive Ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, *dicalcium phosphate anhydrous, hypromellose, maltodextrin, magnesium stearate, microcrystalline cellulose, *mineral oil, *polyethylene glycol (PEG), stearic acid, talk, triacetin. *May also contain.

Questions or comments?

call toll free:1-800-200-6313

Comapre to Senokot active ingredient *

Leader

Senna Laxative Sennosides, 8.6mg Natural Vegetable Laxative for Relief of Constipation 100 Tablets

Distributed by Cardinal Health Dublin, Ohio 43017 CIN 1382639

www.myleader.com 1-800-200-6313

All Leader Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

Product Labeling



Drug Facts

Active ingredient (in each tablet)

Purpose Lavative

Uses ■ relieves occasional constipation (irregularity) ■ generally causes bowel movement in 6-12 hours

Warnings

Do not use | laxative products for longer than 1 week, unless directed by a doctor

Ask a doctor before using if you have ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel movements 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. These may indicate a serious condition.

If pregnant or breast-feeding, ask a health care 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 age adults and children over 12 years of age 2 tablets once a day 4 tablets twice a day children 6 to under 12 years of age 1 tablet once a day 2 tablets twice a day 1 tablet twice a day children 2 to under 6 years of age 1/2 tablet once a day tablet once a day children under 2 years of age ask a doctor ask a doctor

Other information ■ each tablet contains: calcium 25 mg/tablet ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ do not use if imprinted safety seal under cap is broken or missing ■ *This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot®.

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, "dicalcium phosphate anhydrous, hypromellose, maltodextrin, magnesium stearate,"

Drug Facts (continued)

microcrystalline cellulose, *mineral oil, *polyethylene glycol (PEG), stearic acid, talc, triacetin, *May also contain.

Questions or comments? Call toll free 1-800-200-6313

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, 0HIO 43017 CIN 2239689

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LEADER SENNA LAXATIVE

sennosides tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37205-241

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthSENNO SIDES A AND B (UNII: 1B5FPI42EN) (SENNO SIDES - UNII: 3FYP5M0 IJX)SENNO SIDES A AND B8.6 mg

Ingredient Name Strength SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) HYPROMELLOSES (UNII: 3NXW29 V3WO) MALTO DEXTRIN (UNII: 7CVR7L4A2D) MAGNESIUM STEARATE (UNII: 70097M6130) CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) MINERAL OIL (UNII: T5L8 T28 FGP) POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) STEARIC ACID (UNII: 4ELV7Z65AP) TALC (UNII: 7SEV7J4R1U)

TRIACETIN (UNII: XHX3C3X673)

Product Characte	t Characteristics					
Color	brown (BROWN)	Score	no score			
Shape	ROUND (ROUND)	Size	9 mm			
Flavor		Imprint Code	S3;TLC080;S8			
Contains						

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:37205-241-78	100 in 1 BOTTLE			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part334	03/01/2012			

Labeler - Cardinal Health (097537435)

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