

LEADER STOOL SOFTENER PLUS STIMULANT LAXATIVE - docusate sodium, 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 Stool Softener plus Laxative

Active Ingredients (in each tablet)

Docusate Sodium 50mg

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.
- if you are presently taking mineral oil, 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 habits that lasts over 2 weeks.

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. 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 immediately.

Directions

Take only by mouth. Doses may be taken as a single daily does or in divided doses.

- **adults and children 12 years and over:** take 2-4 tablets daily
- **children 6 to under 12 years of age:** take 1-2 tablets daily
- **children 2 to under 6 years of age:** take up to 1 tablet daily
- **children under 2:** ask a doctor

Other information

- **each softgel contains:** sodium 6mg VERY LOW SODIUM
- each tablet contains: **calcium 20mg/tablets**
- store at 15 - 30 degrees C (59-86 degrees F), protect from excessive moisture
- 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 Peri Colace.

Inactive Ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethanol, FDandC Blue no2 Aluminum Lake, FDandC Red No40 Aluminum Lake, hypromellose, magnesium stearate, *maltodextrin, microcrystalline cellulose, *mineral oil, *Opadry II red, polyethylene glycol (PEG) 400, *pregelatinized starch, *silicon dioxide 50s, sodium benzoate, stearic acid and titanium dioxide. *May also contain.

Questions or comments?

call toll free:1-800-200-6313

Compare to the active ingredient Peri Colace

Leader

Stool Softener plus Stimulant Laxative

Docusate Sodium 50mg

Sennosides, 8.6mg

Relieves of Occasional Constipation

100 Softgels

Distributed by Cardinal Health

Dublin, Ohio 43017

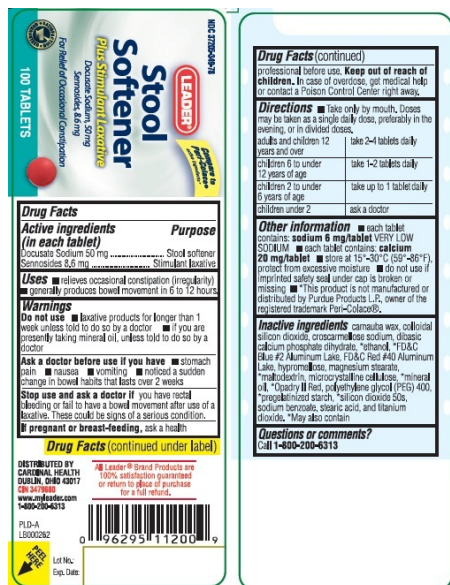
CIN 1382639

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



LEADER STOOL SOFTENER PLUS STIMULANT LAXATIVE

docusate sodium, sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-349
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

MINERAL OIL (UNII: T5L8T28FGP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (RED)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	TLC97;SS1;S44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-349-78	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)

Revised: 3/2012

Cardinal Health