LEADER MAXIMUM STRENGTH LAXATIVE- calcium 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 Maximum Strength Laxative

Active ingredients (in each tablet)

Calcium sennosides 25 mg

Purpose

Stimulant laxative

Use(s)

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor

Ask a doctor before use if you have

noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before use if you

• are taking a prescription drug. Laxatives may affect how other drugs work. Take this product 2 or more hours before or after other drugs

When using this product

• do not use for a period longer than 1 week

Stop use and ask a doctor if

• rectal bleeding or failure to have a bowel movement occur after use of a laxative. These may be signs of 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 immediately.

Directions

- Swallow pill(s) with a glass of water
- Swallow pill(s) whole, do not crush, break or chew.

adults and children 12 years and over	take 2 tablets once or twice daily with a glass of water
children 6 to under 12 years	take 1 tablet once or twice daily with a glass of water
children under 6 years	ask a doctor

Other information

• do not use if individual blister compartments are torn or open

• store at room temperature

Calcium content: 40 mg per tabletMagnesium content: 10 mg per tablet

Inactive ingredients

acacia, anhydrous lactose, calcium sulfate anhydrous, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C Blue #1 aluminum lake, iron oxide, iron oxide black, iron oxide yellow, kaolin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, shellac, sodium lauryl sulfate, stearic acid, sugar, talc, tartaric acid, titanium dioxide.

Principal Display Panel

LEADER®

Compare to the EX-LAX® Maximum Strength Tablets active ingredient*

Maximum Strength

Laxative

Laxative Stimulant

calcium sennosides, 25mg

Gentle, dependable overnight relief of constipation

24 TABLETS

Distributed By: Cardinal Health

Dublin, Ohio 43017

www.myleader.com

CIN 2740934



EX-LAX®	Directions Swallow pill(s) will adults and children 12 years a children 6 to under 12 years children under 6 years	water swallow pill(s) whole, do not crush, break or chew take 2 tablets once or twice daily with a glass of water lake 1 tablet once or twice daily with a glass of water ask a doctor
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LEADER®
MAXIMUM STRENGTH

Laxative

EXP. 101:

NDC 37205-294-62

Purpose Stimulant Laxative



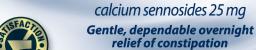
Compare to EX-LAX® EX-LAX® Strength Tablets Maximum Strength Tablets active ingredient*

Drug Facts

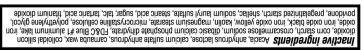
Active ingredients (in each tablet) Oalcium senosides 25 mg

Laxative

Laxative Stimulant



24 TABLETS



Other information ■ do not use if individual blister compartments are tom or open ■ store at room temperature ■ Calcium content: 10mg per tablet.

Drug Facts (continued)

LEADER MAXIMUM STRENGTH LAXATIVE

calcium sennosides tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-294	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SENNO SIDES A AND B (UNII: 1B5FPI42EN) (SENNO SIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	25 mg	

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK)	
CALCIUM SULFATE ANHYDRO US (UNII: E934B3V59H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROUS OXIDE (UNII: G7036X8B5H)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PO VIDO NE (UNII: FZ989 GH94E)	
SHELLAC (UNII: 46N107B71O)	
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	BLUE	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	44;348	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:37205-294-62	2 in 1 CARTON			
1	12 in 1 BLISTER PACK			

Marketing Information				
ı	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