

LAXATIVE PILLS MAXIMUM STRENGTH- sennosides tablet
QUALITY CHOICE (Chain Drug Marketing Association)

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.

DRUG FACTS

Active ingredient (in each tablet)

Sennosides 25 mg

Purpose

Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement un 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 right away.

Directions

- swallow tablet(s) with a glass of water
 - swallow tablet(s) whole, do not crush, break, or chew
-

adults and children 12 years of age and older	take 2 tablets once or twice daily
children 6 to under 12 years of age	take 1 tablet once or twice daily
children under 6 years of age	ask a doctor

Other information

- **each tablet contains:** calcium 50 mg
- very low sodium
- store between 20-25°C (68-77°F)

Inactive ingredients

acacia, ammonium hydroxide*, calcium carbonate*, calcium phosphate dihydrate*, calcium sulfate anhydrous*, carnauba wax, corn starch*, croscarmellose sodium, dicalcium phosphate*, FD&C blue #1, hypromellose*, iron oxide*, iron oxide black, iron oxide yellow*, isopropyl alcohol*, kaolin*, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil*, n-butyl alcohol*, polyethylene glycol, polyvinyl alcohol*, povidone*, propylene glycol*, shellac*, silicon dioxide, sodium lauryl sulfate*, stearic acid, sucrose, talc, titanium dioxide, white wax*

*contains one or more of these ingredients

Questions or Comments?

Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredient in ex-lax® MAXIMUM STRENGTH

Maximum Strength

Laxative

Stimulant Laxative

Sennosides 25 mg

gentle, dependable overnight relief

TABLETS

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

†This product is not manufactured or distributed by Novartis, owner of the registered trademark Ex-Lax®

Distributed by C.D.M.A., Inc.©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Product Label

Drug Facts (continued)
Questions or comments?
 Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by Novartis, owner of the registered trademark Ex-Lax®.

NDC 63868-086-24



Maximum Strength Laxative
Stimulant Laxative
Sennosides 25 mg
 Gentle, Dependable
 Overnight Relief



24 Tablets



6 35515 95280 5

PLD-E16G
 FC003213

Compare to the active ingredient in ex-lax[®] MAXIMUM STRENGTH

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:
 Exp. Date:

Drug Facts (continued)

Active ingredient (in each tablet)
 Sennosides 25 mg
 Stimulant laxative

Purpose
 Stimulant laxative

Uses
 ■ 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

Drug Facts (continued)

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.
 ■ 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 right away.

Directions
 ■ swallow tablet(s) with a glass of water
 ■ swallow tablet(s) whole, do not crush, break, or chew
 adults and children 12 years of age and older take 2 tablets once or twice daily

Drug Facts (continued)

Inactive ingredients acacia, ammonium hydroxide*, calcium carbonate*, calcium phosphate dihydrate*, calcium sulfate anhydrous*, carnauba wax, phosphate*, FD&C blue #1, hypromellose*, iron oxide*, iron oxide black, iron oxide yellow*, isopropyl alcohol*, kaolin*, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil*, n-butyl alcohol*, polyethylene glycol, polyvinyl alcohol*, polydioxane*, propylene glycol*, shellac*, silicon dioxide, sodium lauryl sulfate*, stearic acid, sucrose, talc, titanium dioxide, white wax*
 *contains one or more of these ingredients

Other information
 ■ each tablet contains: calcium 50 mg
 ■ very low sodium
 ■ store between 20-25°C (68-77°F)

children 6 to under 12	take 1 tablet once or twice daily
children under 6	ask a doctor

Drug Facts (continued)

sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-086
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	25 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics

Color	BLUE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL083;S25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-086-24	24 in 1 CARTON	01/31/2016	12/30/2021
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/31/2016	12/30/2021

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2019

QUALITY CHOICE (Chain Drug Marketing Association)