LAXATIVE PILLS MAXIMUM STRENGTH- sennosides tablet Care One (American Sales Company)

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 USP, 25 mg

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

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 aluminum lake, 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*

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the Active Ingredient in ex-lax® Maximum Strength†

MAXIMUM STRENGTH

LAXATIVE PILLS

Sennosides 25 mg

FOR GENTLE, DEPENDABLE OVERNIGHT RELIEF STIMULANT LAXATIVE

Pills

†This product is not manufactured or distributed by GlaxoSmithKline plc, distributor of Ex-Lax®.

^{*}contains one or more of these ingredients

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.

DISTRIBUTED BY FOODHOLD U.S.A. LLC LANDOVER, MD 20785
1-877-846-9949

Product Label

years of age and older adults and children 12

or twice daily take 2 tablets once

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

Directions

medical help or contact a Poison Control Center right away. Keep out of reach of children. In case of overdose, get perore use.

If pregnant or breast-feeding, ask a health professional

Stop use and ask a doctor if

- occur after use of a laxative. These may be signs of a ■ rectal bleeding or failure to have a bowel movement
 - do not use for a period longer than 1 week
 - When using this product

before or after other drugs. other drugs work. Take this product 2 or more hours

■ are taking a prescription drug. Laxatives may affect how Ask a doctor or pharmacist before use if you

Drug Facts (continued)

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

- store between 20-25°C (68-77°F)
- muibos wol ynav ■ each tablet contains: calcium 50 mg
- Other information

	уеагs of age
sak a doctor	children under 6
or twice daily	уеагь оf аде
take 1 tablet once	children 6 to under 12

Drug Facts (continued)

over a period of 2 weeks

Ask a doctor before use if you have

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

SƏSN

Stimulant laxative

Sennosides USP, 25 mg. (in each tablet) Active ingredient

Purpose

Warnings **Drug Facts** (continued)

NDC 41520-492-24

Drug Facts

Compare to the active ingredient in ex-lax® Maximum Strength†

CARE**ONE**

■ noticed a sudden change in bowel habits that persists

Do not use laxative products when abdominal pain,

nausea, or vomiting are present unless directed by a doctor.

MAXIMUM STRENGTH .AXATIVE PIL

Sennosides 25 mg

FOR GENTLE, DEPENDABLE **OVERNIGHT RELIEF STIMULANT LAXATIVE** Actual Size

24 PILLS (25 mg each)

This product is not manufactured or distributed by GlaxoSmithKline plc

istributor of ex-lax®

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Questions or comments? **Orug Facts** (continued)

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PLD-D16I FC004235

CAREONE Maximum Strength Laxative Pills

Exp. Date: Lot No.:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

LAXATIVE PILLS MAXIMUM STRENGTH

sennosides tablet

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Pro	duct	Inform	ation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-492

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	C1
Ingredient Name	Strength
ACACIA (UNII: 5C5403N260)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
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)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics			
Color	blue	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL083;S25
Contains			

P	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:41520- 492-24	2 in 1 CARTON	05/31/2016	05/30/2025	
1		12 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	05/31/2016	05/30/2025

Labeler - Care One (American Sales Company) (809183973)

Revised: 11/2022 Care One (American Sales Company)