# LAXATIVE- sennosides tablet, sugar coated 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.

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#### Leader 44-347

# Active ingredient (in each tablet)

Sennosides USP, 15 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 any other 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 (1-800-222-1222) right away.

#### Directions

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

adults and	2 tablets
children 12	once or
years and over	twice daily
children 6 to	1 tablet once
under	or
12 years	twice daily
children under 6	ask a doctor
vears	ask a doctor

# Other information

- each tablet contains: calcium 45 mg, magnesium 5 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

## Inactive ingredients

acacia, calcium carbonate, carnauba wax, corn starch, dibasic calcium phosphate dihydrate, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, methylparaben, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, propylene glycol, propylparaben, shellac glaze, silicon dioxide, sodium benzoate, sodium lauryl sulfate, sucrose, talc, titanium dioxide

#### Questions or comments?

1-800-426-9391

#### Principal display panel

 $LEADER_{TM}$ 

NDC 70000-0443-1

Regular Strength

Laxative

Sennosides USP, 15 mg

Stimulant Laxative

Gentle Dependable

Constipation Relief

30 TABLETS

COMPARE TO ex•lax® REGULAR STRENGTH active ingredient\*

100% Money

**Back Guarantee** 

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS

#### TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

\*This product is not manufactured or distributed by GSK Consumer Healthcare S.A., owner of the registered trademark ex•lax® Regular Strength.

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6313

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50844 REV0419A34701

**100% Money Back Guarantee** Return to place of purchase.

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Purpose

Active ingredient (in each tablet) Sennosides USP, 15 mg..

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

LEADER 2

NDC 70000-0443-1

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

no print / no varnish area

lot no. & exp. date

**Regular Strength** 

# Laxative

Sennosides USP, 15 mg Stimulant Laxative

Gentle, Dependable Constipation Relief

30 TABLETS



Actual Size

COMPARE TO ex•lax® REGULAR STRENGTH active ingredient\*

100% Money Back Guarantee CIN 5478953 REV. 6/19

100% Money Back Guarantee Retum to place of purchase.

B-0225-347-01 REV0419A34701

#### Questions or comments? 1-800-426-9391

microcrystalline cellulose, polyethylene glycol, polyninyl slcohol, povidone, propylene glycol, propylparaben, shellac glaze, silicon dioxide, sodium benzoate, sodium lauryl sulfate, sucrose, talc, titanium dioxide

Drug Facts (continued)

DUTSIRBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

WWW.myleader.com 1-800-200-6513

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12 years		thisb solwt		
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years and	Ver	twice daily		
adults and	St nərblid:	2 tablets once or		
■ swallow tablet(s) whole; do not crush, break, or chew				
st wollswe ta	let(s) with a glas	s of water		
HALLAAHA				

Drug Facts (continued)

before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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If pregnant or breast-feeding, ask a health professional

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**Warnings** Do not use laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor.

Drug Facts (continued)

Leader 44-347

#### **LAXATIVE**

# sennosides tablet, sugar coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0443
Route of Administration	ORAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII:3FYP5M0 IJX)	SENNOSIDES	15 mg			

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438 O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PO VIDO NE (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46 N107B710)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	BROWN (Tan)	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	44;347	
Contains				

P	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date

	Application Number or Monograph Citation	Marketing Start Date 03/01/2019	Marketing End Date
		Marketing Start Date	Marketing End Date
or mate			
ormati	on		
15 in 1 BLI	STER PACK; Type 0: Not a Combination Product		
2 in 1 CAR	TON	0 3/0 1/20 19	
	15 in 1 BLI		15 in 1 BLISTER PACK; Type 0: Not a Combination Product

# Labeler - Cardinal Health (097537435)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(70000-0443)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(70000-0443)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	PACK(70000-0443)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(70000-0443)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(70000-0443)

Revised: 10/2019 Cardinal Health