## LAXATIVE MAXIMUM STRENGTH- sennosides tablet, sugar coated Topco Associates, LLC

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## TopCare 44-348 Delisted

## 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 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 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 and	2 tablets once or twice
over	daily
children 6 to linder 17 years	1 tablet once or twice daily
children under 6 years	ask a doctor

#### Other information

- each tablet contains: calcium 40 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, FD&C blue #1 aluminum lake, iron oxide black, 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?

1-888-423-0139

## Principal Display Panel

**+TopCare** ® health

NDC 36800-305-08

COMPARE TO EX•LAX® MAXIMUM STRENGTH ACTIVE INGREDIENT<sup>†</sup>

MAXIMUM STRENGTH

#### Laxative

SENNOSIDES USP, 25 mg • STIMULANT LAXATIVE

- Senna Ingredient
- Gentle, Dependable Constipation Relief

#### 24 COATED TABLETS

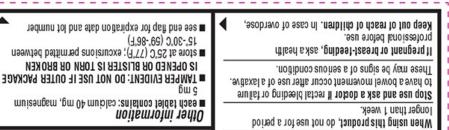
actual size

# 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® Maximum Strength.

✓ QUALITY GUARANTEED 50844 ORG041934808

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TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



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

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

get medical help or contact a Poison Control Center

**Drug Facts** (continued)

or after other drugs. drugs work. Take this product 2 or more hours before taking any other drug. Laxatives may affect how other Ask a doctor or pharmacist before use if you are

change in bowel habits that persists over a period of 2 Ask a doctor before use if you have noticed a sudden

nausea, or vomiting are present unless directed by a Do not use laxative products when abdominal pain, Marnings

Urug Facts (continued)

B-1910-348-08-R 0RG041934808

IThis product is not manufactured or distributed by GSK Consumer Healthcare S.A., owner of the registered trademark ex-lax® Maximum Strength.

✓ QUALITY GUARANTEED

Lot & Exp. Date

No print Area

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

Stimulant laxative, Sennosides USP, 25 mg (in each tablet)

Purpose

COMPLETE PRODUCT INFORMATION

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

**Drug Facts** (continued)

NDC 36800-305-08

Active ingredient

Drug Facts

COMPARE TO EX•LAX® MAXIMUM STRENGTH ACTIVE INGREDIENT<sup>†</sup>



**MAXIMUM STRENGTH** 

# Laxative

SENNOSIDES USP, 25 mg • STIMULANT LAXATIVE

- Senna Ingredient
- Gentle, Dependable Constipation Relief

information or call 1-888-423-0139

actual

24 COATED TABLETS

Denzoate, sodium laury sulfate, sucrose, talc, titanium propylparaben, shellac glaze, silicon dioxide, sodium polyvinyl alcohol, povidone, propylene glycol,

(beunitnoo) **stor4 puri** 

microcrystalline cellulose, polyethylene glycol, black, magnesium stearate, methylparaben, carnauba wax, corn starch, dibasic calcium phosphate dihydrate,  $\Theta$  &C blue #1 aluminum lake, iron oxide Inactive ingredients acacia, calcium carbonate,

**Drug Facts** (continued)

Questions or comments? 1-888-423-0139

44-348

DISTRIBUTED BY
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1 ©TOPCO LINKA0221
1 OUESTIONS? 1-888-423-0139
1 topcare@topco.com

www.topcarebrand.com

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#### sennosides tablet, sugar coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-305

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

**Contains** 

Ingredient Name

Basis of Strength

SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)

SENNOSIDES (25 mg

**Inactive Ingredients** Strength **Ingredient Name ACACIA** (UNII: 5C5403N260) **CALCIUM CARBONATE** (UNII: H0G9379FGK) CARNAUBA WAX (UNII: R12CBM0EIZ) STARCH, CORN (UNII: O8232NY3SJ) **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) FERROSOFERRIC OXIDE (UNII: XM0M87F357) MAGNESIUM STEARATE (UNII: 70097M6I30) METHYLPARABEN (UNII: A2I8C7HI9T) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A) POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59|990) POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) PROPYLPARABEN (UNII: Z8IX2SC1OH) **SHELLAC** (UNII: 46N107B710) **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) **SODIUM BENZOATE** (UNII: OJ245FE5EU) **SODIUM LAURYL SULFATE** (UNII: 368GB5141)) SUCROSE (UNII: C151H8M554) TALC (UNII: 7SEV7J4R1U)

Product Characteristics			
Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;348

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:36800- 305-08	2 in 1 CARTON	03/19/2021	10/27/2024
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

03/19/2021

10/27/2024

## Labeler - Topco Associates, LLC (006935977)

OTC Monograph Drug 505G(a)(3)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(36800-305)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	pack(36800-305)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(36800-305)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(36800-305)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(36800-305)

Revised: 10/2023 Topco Associates, LLC