

**LAX-TIME- sennosides tablet, sugar coated**  
**TIME CAP LABORATORIES, INC**

*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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**195R Sennosides tablets USP 25 mg sugar coated off-white**

Each Tablet contains:

CALCIUM SENNOSIDES 25 mg

INACTIVE INGREDIENTS: acacia, calcium sulfate anhydrous, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue#1, iron oxide, iron oxide black, iron oxide yellow, kaolin, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, shellac, stearic acid, sugar, talc, titanium dioxide

stool softner, laxative

Directions:

Take preferably at bedtime or as directed by a doctor. If you do not have a comfortable bowel movement by the second day, increase dose by one tablet (not to exceed maximum dosage) or decrease dose until you are comfortable.

Adults and children 12 years and over - starting dosage: 2 tablets once a day maximum dosage: 4 tablets twice a day

Children 6 to under 12 years - starting dosage: 1 tablet once a day maximum dosage: 2 tablets twice a day

Children 6 to under 12 years - starting dosage: 1/2 tablet once a day maximum dosage: 1 tablet twice a day

Children under 2 years - Ask a doctor

Uses:

Relieves occasional constipation (irregularity); generally causes bowel movement in 6-12 hours

WARNINGS:

Do not use this product

If you are presently taking mineral oil, unless directed by a doctor

Laxative products for longer than 1 week unless directed by a doctor



Code # 195R

195R

P.O. # ????????

PRODUCT # ??????????

**Time-Cap Labs Inc**

7 Michael Avenue Farmingdale NY 11735

BULK SHIPMENT INTENDED FOR MANUFACTURING,  
PROCESSING OR REPACKAGING

TCL Control # ???????

THEORETICAL QUANTITY: ??????????

CTN# ??? OF ??? CTNS.

NDC 49483-083-00

Prod'l SENNOSIDES TABLETS USP, 25 MG (SUGAR  
COATED, BLUE)

Each Tablet Contains: CALCIUM SENNOSIDES 25 MG

IMPRINT: TCL 083

STORE AT 25°C (77°F) - Excursions permitted between  
15°-30°C (59°-86°F) IN ORIGINAL BULK CONTAINERS

REPACKAGE IMMEDIATELY UPON RECEIPT

**IMPORTANT**

This is a bulk shipment intended to be repackaged and labeled immediately upon receipt in strict conformance with the applicable requirements of the Food, Drug and Cosmetic Act, and regulations thereunder or the laws and regulations of the country of destination.

Upon request Time-Cap Labs will supply stability supported packaging specifications. Our responsibility ceases upon removal of the product from the bulk containers or failure to request or follow Time-Cap Labs packaging and/or labeling specifications.

**LAX-TIME**

sennosides tablet, sugar coated

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:49483-083

**Route of Administration**

ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>sennosides a and b</b> (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	sennosides a and b	25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>CALCIUM SULFATE ANHYDROUS</b> (UNII: E934B3V59H)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>RAW SUGAR</b> (UNII: 8M707QY5GH)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>ACACIA</b> (UNII: 5C5403N26O)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL083
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-083-00	50000 in 1 CARTON; Type 0: Not a Combination Product	08/30/2018	
2	NDC:49483-083-09	95 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/30/2018	

**Labeler** - TIME CAP LABORATORIES, INC (037052099)

## Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(49483-083)

Revised: 2/2023

TIME CAP LABORATORIES, INC