

SENNOSIDES- 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.

190R Sennosides tablets USP 15 mg sugar coated off-white

Each Tablet contains:

Sennosides 15 mg

INACTIVE INGREDIENTS: acacia, calcium sulfate anhydrous, carnauba wax, corn starch, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue#1, FD&C Red#40, FD&C Yellow#6, iron oxide, iron oxide black, iron oxide yellow, Kaolin, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol(PEG 400), povidone, Shellac, 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

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

Code # 190R

PLD 190R

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

Product #: TEX15

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 49483-079-00

Product: SENNOSIDES TABLETS USP, 15 MG (SUGAR
COATED, OFF-WHITE)

Each Tablet Contains **CALCIUM SENNOSIDES 15 MG**
IMPRINT: TCL 079
MADE IN THE USA

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.

Ship To:

REV: 11 14

SENNOSIDES

sennosides tablet, sugar coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-079
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	15 mg

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
ACACIA (UNII: 5C5403N26O)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
RAW SUGAR (UNII: 8M707QY5GH)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	TCL079
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-079-00	50000 in 1 CARTON; Type 0: Not a Combination Product	08/30/2018	
2	NDC:49483-079-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2018	

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)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(49483-079)

Revised: 11/2019

TIME CAP LABORATORIES, INC