

SENNA TIME S- docusate sodium-sennosides tablet, film 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.

192R Timely 49483 081 Docusate sodium 50 mg Sennosides 8.6 mg tablets

DRUG FACTS

Active ingredients (in each tablet)

Docustate sodium 50 mg

Sennosides 8.6 mg

Purposes

Stool softener

Stimulant laxative

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

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- a sudden change in bowel movements that persists over 2 weeks

Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative.

These could be signs of a serious condition

If pregnant or breast-feeding, ask a health professional before use.

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

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 (do not exceed maximum dosage) or decrease dose until you are comfortable

age	starting dosage	maximum dosage
adults and children 12 years of age and older	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	½ tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains: calcium 20 mg, sodium 6 mg (LOW SODIUM)
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, titanium dioxide

Questions or comments?

Call 1-877-290-4008

Timely
¹Compare to the active ingredients in SENOKOT-S®

Senna-S Laxative
Docosate sodium, 50 mg
Sennosides, 8.6 mg
Stool Softener | Stimulant Laxative
Natural Vegetable Laxative
Gentle, Overnight Relief

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

1000 Tablets Actual Size

NDC 49483-081-10

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

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 Sennosides 8.6 mg Stimulant laxative

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Drug Facts (continued)
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 (do not exceed maximum dosage) or decrease dose until you are comfortable

age	starting dosage	maximum dosage
adults and children 12 years of age and older	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

Other information
 ■ each tablet contains: calcium 20 mg, sodium 6 mg (LOW SODIUM)
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Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, titanium dioxide

Questions or comments? Call 1-877-290-4008
 *This product is not manufactured or distributed by Parfide Products L.P., owner of the registered trademark Senokot-S®.
 Manufactured by Time-Cap Labs, Inc.
 7 Micobar Avenue, Farmingdale, NY 11735

LOT #: 3 49483 08110 7
EXP. DATE: 7

Varnish Omit Area

docusate sodium-sennosides tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-081
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	8.6 min

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	TCL081
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-081-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2018	
2	NDC:49483-081-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2018	
3	NDC:49483-081-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/14/2012	

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(49483-081)

Revised: 12/2021

TIME CAP LABORATORIES, INC