DOCUSATE SENNOSIDES- docusate sennosides tablet, film coated
DIRECTRX
Reference Label Set Id: 835a2cd4-4801-3e40-e053-2a91aa0abfea

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.

DOCUSATE SENNOSIDES

Each Tablet contains:

Docustate sodium 50 mg

Sennosides 8.6 mg

INACTIVE INGREDIENTS: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, d-c yellow#10 aluminum lake fd&c yelow#6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, 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 to2 to under 6 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

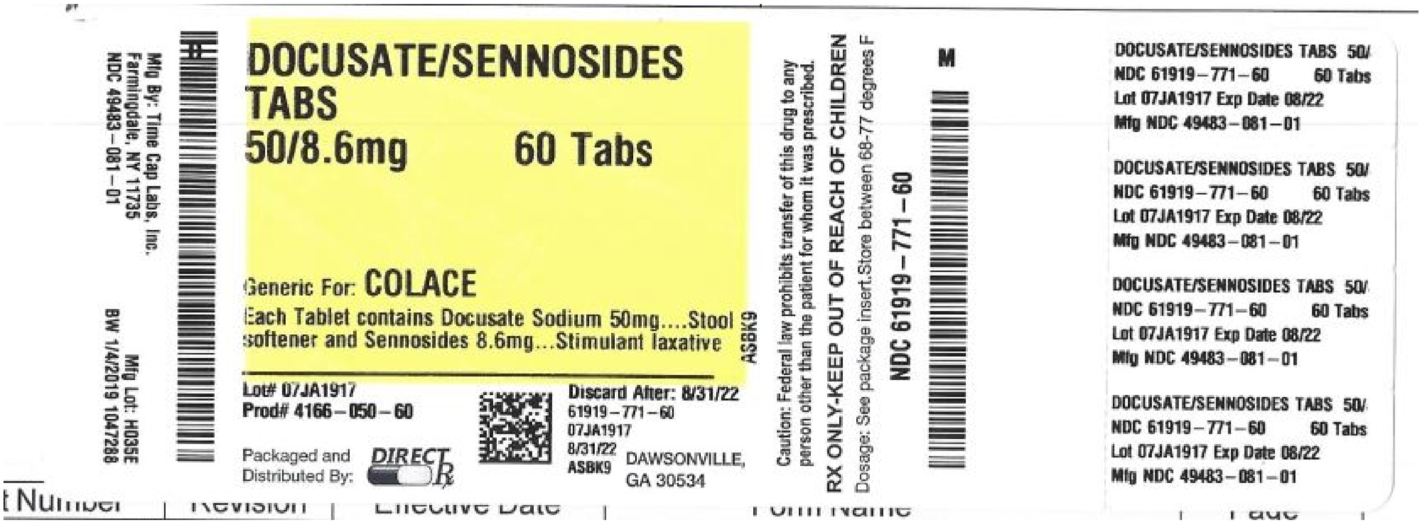
WARNINGS:

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.



DOCUSATE SENNOSIDES

docusate sennosides tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-771(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 mg

Inactive Ingredients

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

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:61919-771-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/29/2019	

Labeler - DIRECTRX (079254320)

Registrant - DIRECTRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECTRX		079254320	repack(61919-771)

Revised: 12/2019 DIRECTRX