SENNOSIDES AND DOCUSATE SODIUM- sennosides and docusate sodium tablet
McKesson Packaging Services a business unit of McKesson Corporation

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.

Drug Facts

Active ingredient

Docusate Sodium 50mg

Sennosides 8.6 mg

Purpose

Docusate Sodium.....Stool Softener

Sennosides.....Stimulant Laxative

Keep Out of Reach of Children

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 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 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 the maximum dosage) or decrease dose until you are comfortable.

Age	Starting Dose	Maximum Dose
Adults and children 12 years of age and over	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 tablets twice a day
Children under 2 years	ask a doctor	ask a doctor

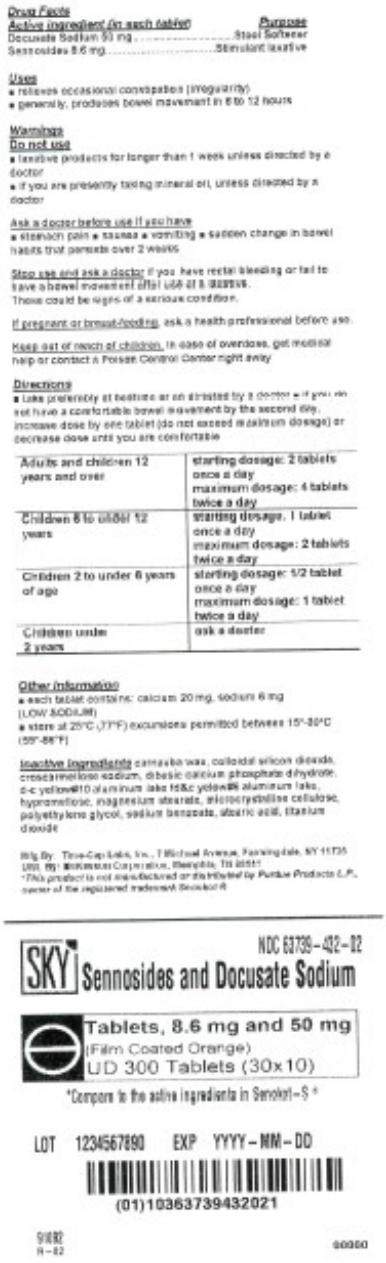
Other Information

- each tablet contains calcium 20mg, sodium 6mg (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

Package/Label Principal Display Panel



Drug Facts

Active ingredient (in each tablet) — Purpose

Docusate Sodium 50 mg — Stool Softener

Sennosides 8.6 mg — Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally, produces bowel movement in 6 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are presently taking mineral oil, unless directed by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- sudden change in bowel habits 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 stimulant laxative. These could 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

- 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

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

Mfg By: Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735
Dist. By: [illegible] Corporation, Memphis, TN 38141
*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot-S

SKY
NDC 63739-432-02
Sennosides and Docusate Sodium
Tablets, 8.6 mg and 50 mg
(Film Coated Orange)
UD 300 Tablets (30x10)
*Compare to the active ingredients in Senokot-S *
LOT 1234567890 EXP YYYY-MM-DD
(01)10363739432021
SHEET
H-02
60000

SENNOSIDES AND DOCUSATE SODIUM

sennosides and docusate sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63739-432(NDC:49483-081)
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	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

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, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
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:63739-432-10	10 in 1 BOX, UNIT-DOSE	11/10/2007	07/31/2021
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63739-432-01	25 in 1 BOX, UNIT-DOSE	11/10/2007	07/31/2021
2		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63739-432-04	25 in 1 BOX	11/10/2007	05/31/2013
3		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:63739-432-02	30 in 1 BOX	07/28/2021	
4		10 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
OTC monograph not final	part334	10/11/2007	

Labeler - McKesson Packaging Services a business unit of McKesson Corporation (140529962)

Establishment

Name	Address	ID/FEI	Business Operations
Legacy Pharmaceutical Packaging, LLC		143213275	repack(63739-432) , relabel(63739-432)

Revised: 7/2021 McKesson Packaging Services a business unit of McKesson Corporation