SENNA-DOC- senna and docusate sodium tablets, 8.6 mg and 50 mg tablet, coated
3014704014

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.

Senna-Doc - Senna and Docusate Sodium Tablets, 8.6 mg & 50 mg

Drug Facts

Active ingredients Purpose (in each tablet) Purpose

Docusate sodium 50 mg.....Stool softner

Sennosides 8.6 mg.....Laxative

Uses

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

Warnings

Do not use

- if you are now 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
- noticed a sudden change in bowel habits that lasts 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 may indicate 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

- **adults and children 12 years of age or older - 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 - starting dosage:** 1/2 tablet once a day, **maximum dosage:** 1 tablet twice a day
- **children under 2 years - starting dosage:** ask a doctor, **maximum dosage:** ask a doctor

Other information

- each tablet contains: calcium 21 mg
- each tablet contains: sodium 3 mg VERY LOW SODIUM
- store at 25ºC (77ºF); excursions permitted between 15°-30°C (59°-86°F)
- read all product information before using
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

croscarmellose sodium, colloidal silicon dioxide, dicalcium phosphate, D&C Yellow # 10, FD&C Yellow # 6, hypromellose, microcrystalline cellulose, magnesium stearate, maltodextrin, polyethylene glycol, stearic acid, titanium dioxide

Questions or comments?

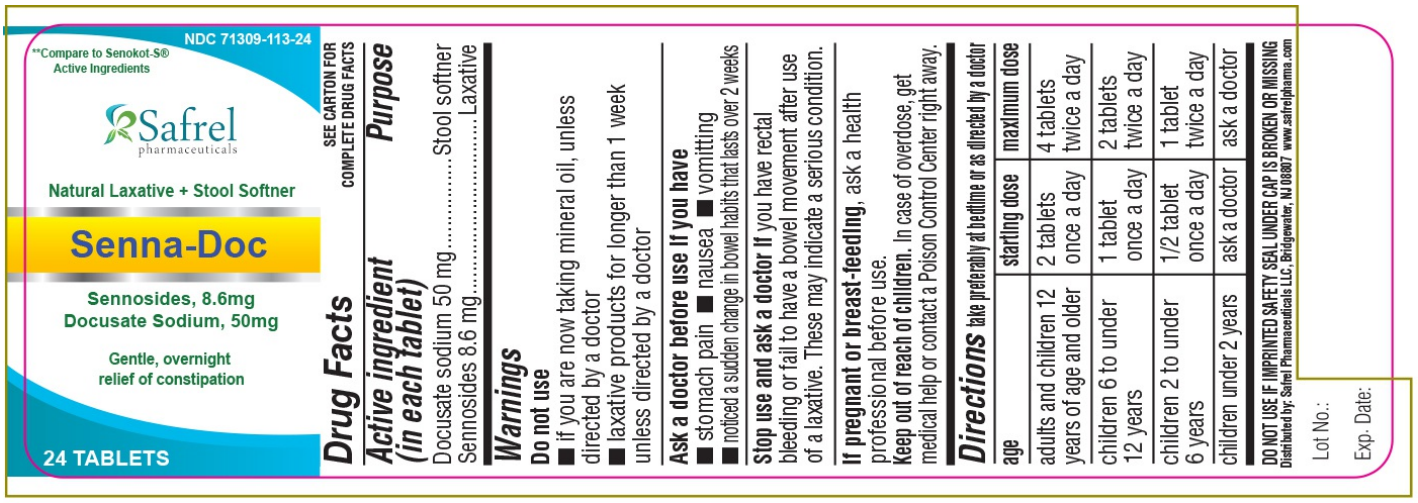
Call toll free 1-844-384-3723 Monday through Friday 9AM – 5PM EST or www.safrelpharma.com

PRINCIPAL DISPLAY PANEL

Compare to Senokot-S® Active Ingredients

***This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot-S®.**

Senna and Docusate Sodium Tablets, 8.6 mg and 50 mg



SENNA-DOC

senna and docusate sodium tablets, 8.6 mg and 50 mg tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-113
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	S35
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-113-25	25 in 1 BOX	04/08/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:71309-113-50	50 in 1 BOX	04/08/2016	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:71309-113-02	2 in 1 POUCH	04/08/2016	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:71309-113-10	1000 in 1 BOTTLE	04/08/2016	
4	NDC:71309-113-05	500 in 1 BOTTLE		
4	NDC:71309-113-24	24 in 1 BOTTLE		
4		1 in 1 CARTON; 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	03/07/2016	

Labeler - 3014704014 (080566287)