SENNA AND DOCUSATE SODIUM - senna and docusate sodium tablet, film coated Sunrise Pharmaceutical 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.

Unknown Title

OTC - ACTIVE INGREDIENT

Docusate sodium 50 mg Sennosides 8.6 mg

OTC - PURPOSE

Stool softener and Stimulant laxative

INDICATIONS AND USAGE

- relieves occasional constipation (irregularity)
- generally produces a bowel movement within 6 to 12 hours

WARNINGS

Do not use:

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

OTC - ASK A DOCTOR BEFORE USE IF YOU HAVE

- Stomach pain
- Nausea
- Vomiting
- Noticed a sudden change in bowel habits that lasts over 2 weeks

OTC - 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.

OTC - IF PREGNANT OR BREAST FEEDING

Ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DOSAGE AND ADMINISTRATION

• Take preferably at bedtime or as directed by a doctor

age	starting dosage	maximum dosage
adults and children 12 years of age or 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 30 mg, sodium 3 mg VERY LOW SODIUM
- Do not use if imprinted safety seal under cap is missing or damaged.
- Store at 25° C (77° F); excursions permitted between 15° C-30° C (59° -86° F).
- Keep tightly closed.

INACTIVE INGREDIENT

Colloidal silicon dioxide, dicalcium phosphate, D&C yellow No 10 Aluminum Lake, ethanol, FD&C yellow No 6 Aluminum Lake, hydroxypropyl methyl cellulose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, pregelatinized starch, silicon dioxide, sodium benzoate, stearic acid, talc, titanium dioxide

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 11534-090-60

Senna 8.6mg **Docusate Sodium 50mg**

For Gentle, Predictable Relief of Constipation Natural Vegetable Laxative plus Stool Softener



60 Tablets

in each tablet)

relieves occasional constipation (irregularity) generally produces a bowel movement within 6 to 12 hours

Do not use

| laxative products for longer than 1 week unless told to do so by a doctor
| if you are presently taking mineral oil, unless told to do so by a doctor

Drug Facts (Continued on Back of Label) REV, 01/11

Manufactured by: Sunrise Pharmaceutical, Ir Rahway, NJ 07065 USA

(p	if you have e a bowel ative,	or breast-feeding, ask a sssional before use. each of children. In case get medical help or contact trol Center right away.	as directed	maximum dosage	e 4 tablets twice a day	a 2 tablets twice a day	1 tablet twice a day	ask a doctor	um 30 mg, DluM flety seal naged. sions colloidal nosphate, m Lake, Aluminum cellulose, crystalline thylene thylene silicon stearic acid,
Facts (Continued)	se and ask a doctor if you bleeding or fail to have a bo nent after use of a laxative, could be signs of a serious ion.	breast-feeding, conal before use. ch of children. In medical help or c I Center right awa	it bedtime or	starting dosage	2 tablets once a day	1 tablet once a day	1/2 tablet once a day	ask a doctor	formation t contains: calcium 30 mg, g VERY LOW SODIUM e if imprinted safety seal s missing or damaged. 3°C (77°E); excursions ween 15°-30°C (59°-86°F) tly closed. ingredients colloidal de, dicalcium phosphate, No.10 Aluminum Lake, &C yellow No.6 Aluminum xypropylmethyl cellulose, stearate, microcrystalline ineral oil, polyethylene elatinized starch, silicon ilium benzoate, stearic acid
Drug Facts	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.	e de la	Directions ■ take preferably at bedtime or as directed by a doctor	age	adults and children 12 years of age or older	children 6 to under 12 years	children 2 to under 6 years	children under 2 years	er inflam 3 mg m 2 mg m 2 mg m 2 mg

SENNA AND DOCUSATE SODIUM

senna and docusate sodium tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11534-090

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX)	SENNOSIDES	8.6 mg

Inact			

mactive ingredients	
Ingredient Name	Strength
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TALC (UNII: 7SEV7J4R1U)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics							
Color	ORANGE	Score	no score				
Shape	ROUND	Size	10 mm				
Flavor		Imprint Code	S90				
Contains							

F	Packaging									
#	Item Code	Package Description	Marketing Start Date	Marketing End Date						
1	NDC:11534-090-60	60 in 1 BOTTLE								
2	NDC:11534-090-01	100 in 1 BOTTLE								

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part334	07/26/2007						

Labeler - Sunrise Pharmaceutical Inc (168522378)

$\pmb{Registrant - \text{Sunrise Pharmaceutical Inc (168522378)}}$

Revised: 8/2013 Sunrise Pharmaceutical Inc