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

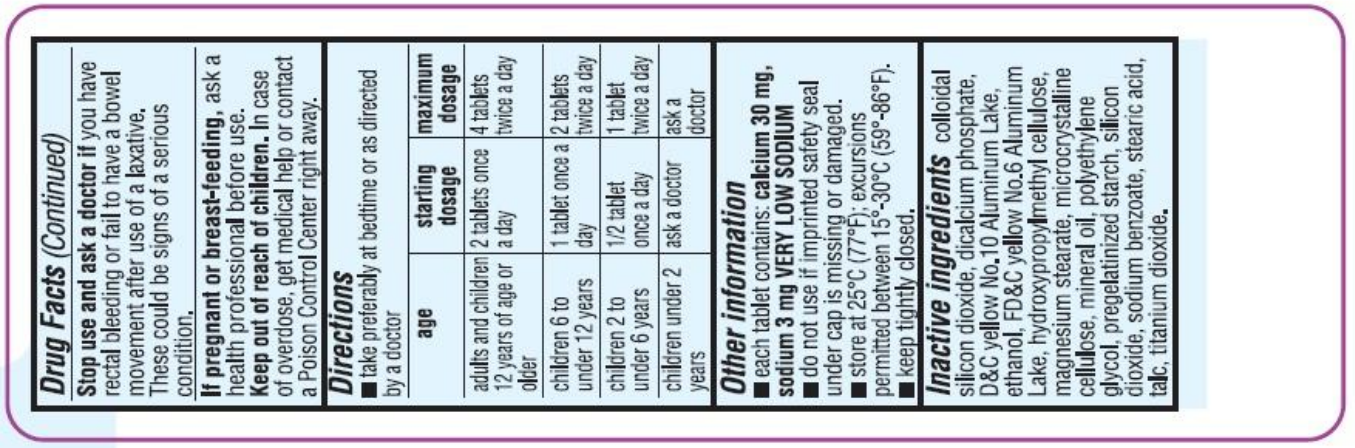
OTHER INFORMATION

- 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



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		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

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

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)

Registrant - Sunrise Pharmaceutical Inc (168522378)

Revised: 8/2013 Sunrise Pharmaceutical Inc