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.

Senna and Docusate Sodium Film Coated Red Tablets 8.6 mg/ 50 mg Laxative

OTC - ACTIVE INGREDIENT

Docusate sodium 50 mg, Sennoside 8.6 mg.

OTC - PURPOSE

Stimulant laxative.

INDICATIONS AND USAGE

For temporary relief of occasional constipation and irregularity.

This product generally produces bowel movement in 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 DOCTOR

Before use if you have:

Stomach pain, nausea or vomiting

Noticed a sudden change in bowel habits that lasts over 2 weeks.

OTC - STOP USE

If you have rectal bleeding or fail to have bowel movement after use of a laxative. This could be a serious condition.

OTC - PREGNANCY 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

Drink with a full glass of water with each dose

Adults and children 12 years and over	take 2 - 4 tablets daily
Children 6 to under 12 years	take 1 - 2 tablets daily
Children 2 to under 6 years	take up to 1 tablet daily
Children under 2 years of age	Ask a doctor

OTHER INFORMATION

Each tablet contains: calcium 30 mg, sodium 3 mg VERY LOW SODIUM.

Do not use if the imprinted safety seal under cap is missing or damaged.

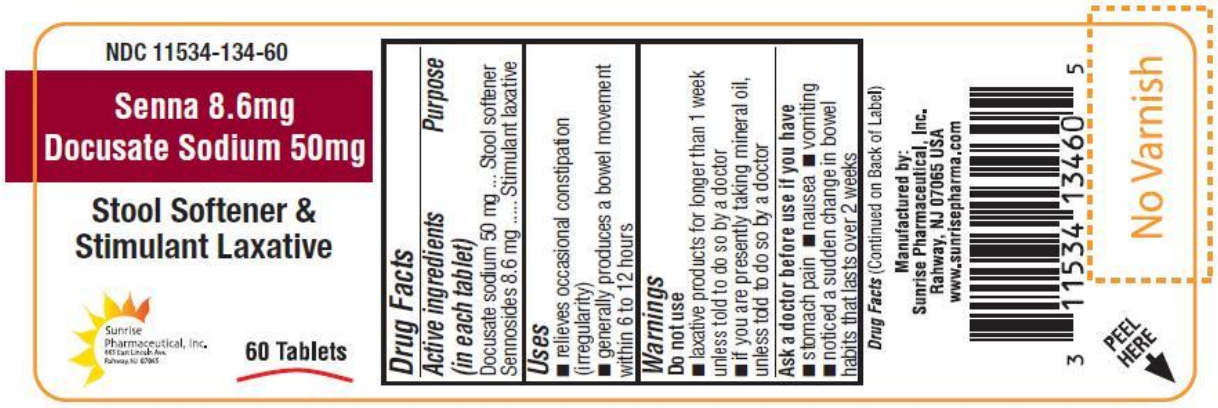
Store at at 25°C (77°F); excursions permitted between 15(-30(C (59(-86(F)

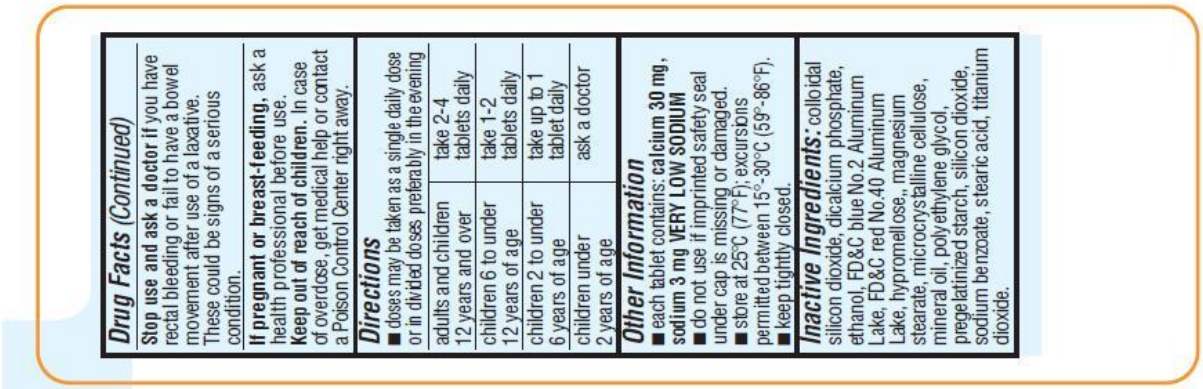
Keep tightly closed.

INACTIVE INGREDIENT

Colloidal silicon dioxide, dicalcium phosphate, ethanol, FD&C blue #2, FD&C red #40, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, pregelatinized starch, silicon dioxide, sodium benzoate, stearic acid, 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:11534-134
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)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	S134
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11534-134-60	60 in 1 BOTTLE		
2	NDC:11534-134-05	57603 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK		

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)

Revised: 8/2013 Sunrise Pharmaceutical Inc