DOCUSATE SODIUM AND SENNA- docusate sodium and senna tablet, film coated
DIRECT RX

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.

DOCUSATE SODIUM AND SENNA

OTC - ACTIVE INGREDIENT SECTION

Active ingredients (in each tablet)
Docusate Sodium 50 mg
Sennosides 8.6 mg

OTC - PURPOSE SECTION

Purposes
Stool Softener
Stimulant Laxative

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

KEEP OUT OF REACH OF CHILDREN SECTION

INDICATIONS & USAGE SECTION

Uses
- relieves occasional constipation
- generally produces bowel movement in 6-12 hours

WARNINGS SECTION

Warnings

OTC - DO NOT USE SECTION

Do not use
- for longer than one week
- if you are taking mineral oil
- when abdominal pain, nausea or vomiting are present

OTC - ASK DOCTOR SECTION

Ask a doctor before use if you have noticed a sudden change in bowel habits that lasts over two weeks

OTC - ASK DOCTOR/PHARMACIST SECTION

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

OTC - STOP USE SECTION

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use of this product.

These may indicate a serious condition.

OTC - PREGNANCY OR BREAST FEEDING SECTION

If pregnant or breast-feeding, ask a health professional before use.
Close

DOSAGE & ADMINISTRATION SECTION

Directions
adults and children 12 years and over: 2-4 tablets once daily or in divided doses
children 6 to under 12 years: 1-2 tablets once daily or in divided doses
children 2 to under 6 years: 1/2-1 tablet once daily or in divided doses
children under 2 years: ask a doctor

STORAGE AND HANDLING SECTION

Other information
each tablet contains: calcium 20 mg, sodium 6 mg (LOW SODIUM)
store at 20°-25°C (68°-77°F)

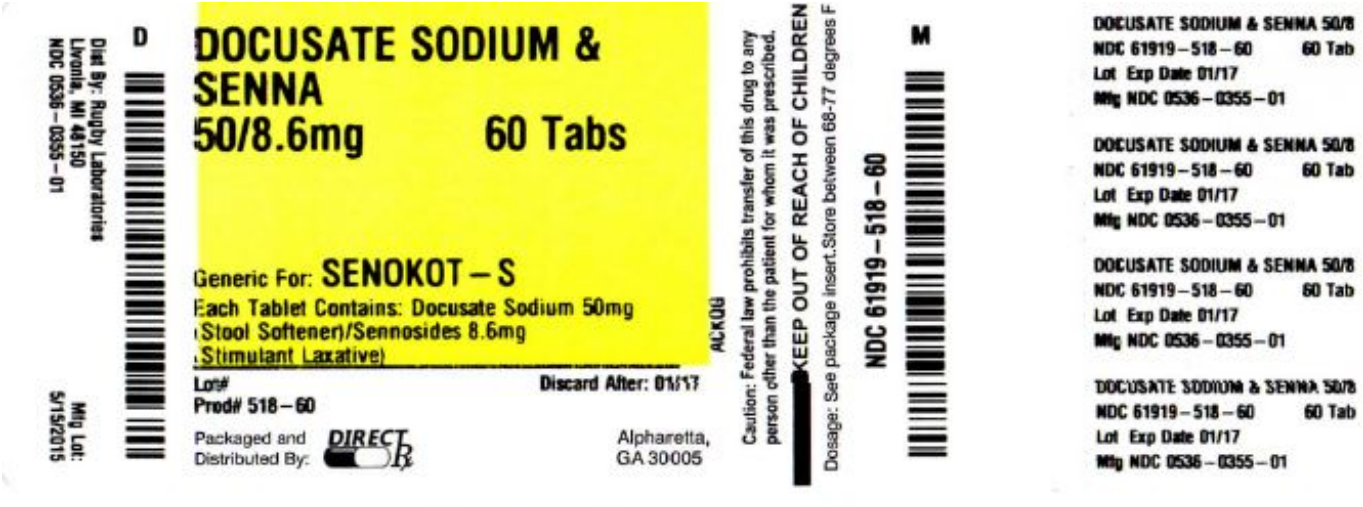
INACTIVE INGREDIENT SECTION

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD-C blue #2 aluminum lake, FD-C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG), sodium benzoate, stearic acid, titanium dioxide

OTC - QUESTIONS SECTION

Questions or comments?
call 1-800-645-2158, 9 am - 5 pm ET, Monday - Friday

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



DOCUSATE SODIUM AND SENNA

docusate sodium and senna tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-518(NDC:0536-0355)
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	purple	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	TCL;131
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-518-60	60 in 1 BOTTLE		
1	NDC:61919-518-30	30 in 1 BOTTLE		
1	NDC:61919-518-71	100 in 1 BOTTLE; 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	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-518) , repack(61919-518)

Revised: 11/2015 DIRECT RX