DOCUSATE SODIUM- docusate sodium tablet, film coated
DIRECTRX

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

Sennosides from Senna Concentrate 8.6mg

Docusate Sodium 50mg

Laxative

Stool Softner

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

Do not use

laxative products for longer than 1 week unless directed by a doctor
if you are taking mineral oil, 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 continues over a period of 2 weeks

Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after the use of a laxative. These may indicate a serious condition.

If pregnant or breast feeding,

ask a healthcare professional before use.

Keep out of reach of children.

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

take preferably at bedtime or as directed by a doctor

age

starting dosage

maximum dosage

Adults and children 12 years and over

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

1/2 tablet once a day

1 tablet twice a day

Children under 2 years

ask a doctor

ask a doctor

each tablet contains 10 mg of calcium, sodium 5 mg
store at 25°(77°F); excursions permitted between 15o-30oC (59o-86oF)

crosscarmellose Sodium, D&C Yellow# 10, dicalcium phosphate, FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, sodium benzoate, talc, titanium dioxide

866) 562-2756 Mon-Fri 8 AM to 4 PM EST

Directions:

Take preferably at bedtime or as directed by a doctor. If you do not have a comfortable bowel movement by the second day, increase dose by one tablet (not to exceed maximum dosage) or decrease dose until you are comfortable.

Adults and children 12 years and over - 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

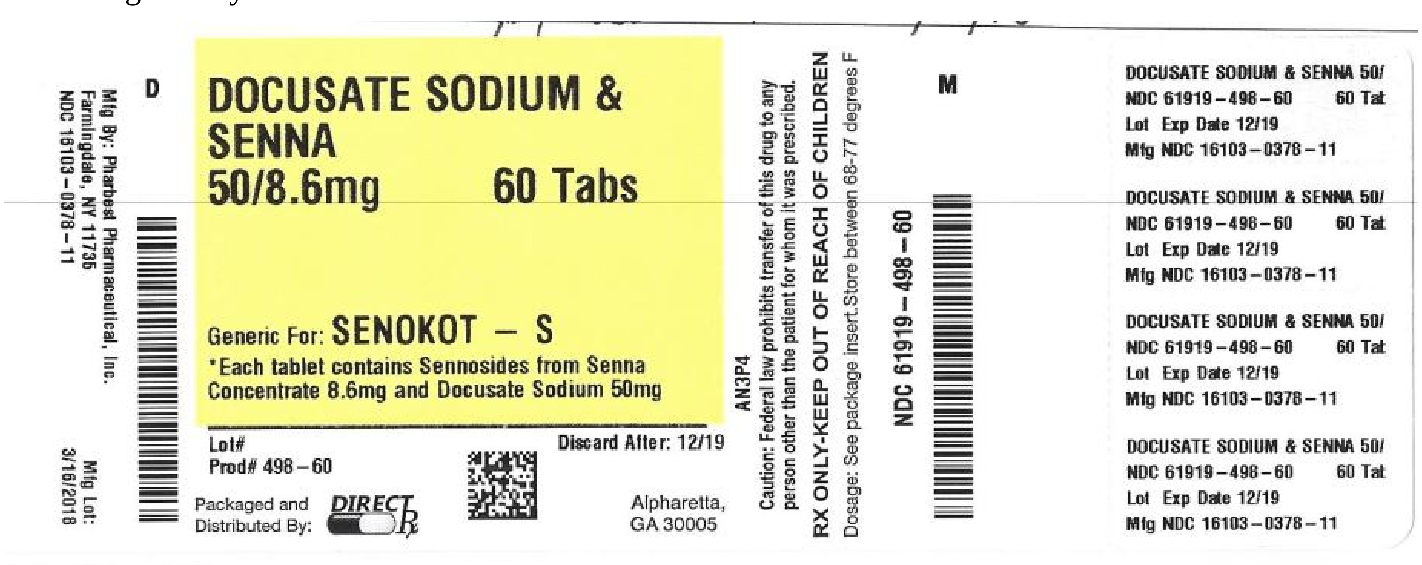
Children to2 to under 6 years - starting dosage: 1/2 tablet once a day maximum dosage: 1 tablet twice a day

Children under 2 years - Ask a doctor

Uses:

Relieves occasional constipation (irregularity); generally causes bowel movement in 6-12 hours

keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.



DOCUSATE SODIUM

docusate sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-498(NDC:16103-378)
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**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	orange (ORANGE COLOR)	**Score**	no score
Shape	ROUND (ROUND TABLET)	**Size**	10mm
Flavor		**Imprint Code**	PH32
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-498-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/05/2018	

Labeler - DIRECT RX (079254320)

Registrant - DIRECTRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECTRX		079254320	repack(61919-498)

Revised: 4/2019 DIRECTRX