# SENEXON-S - docusate sodium -sennosides tablet, coated H.J. Harkins Company, 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.

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Active ingredients (in each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

# ASK A DOCTOR BEFORE USE IF YOU HAVE A SUDDEN CHANGE IN BOWEL HABITS THAT LASTS OVER TWO WEEKS

Ask a doctor or pharmacist berfore use if you are taking any other drug. Laxatives may affect how other drugs work.

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

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

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

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

call 1 800 645-2158 9 am - 5 pm Monday - Friday

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.

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium

D-C yellow #10 aluminum lake, dibasic calcium phosphate

dihydrate, FD-C yellow #6 aluminum lake, hypromellose,

magnesium stearate, microcrystalline cellulose, polyethylene

glycol, sodium benzoate, stearic acide, Titanium dioxide

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 (do not exceed maxiumum dosage)

## Dosage and Administration

Adults and children 12 years and over - 2 tablets once a day - maximum dosage - 4 tablets twice a day children 6 to under 12 years - 1 tablet once a day maximum dosage - 2 tablets twice a day children 2 to under 6 years - 1/2 tablet once a day - maximum dosage - 1 tablet twice a day children under 2 years - ask a doctor

## RELIEVES OCCASIONAL CONSTIPATION

#### GENERALLY PRODUCES BOWEL MOVEMENT IN 6-12 HOURS



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### **SENEXON-S**

docusate sodium -sennosides tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-675(NDC:0536-4086)
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 a and b (UNII: 1B5FPI42EN) (sennosides a and b - UNII:1B5FPI42EN)	sennosides a and b	8.6 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	TCL081
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:52959-675-30	30 in 1 BOTTLE, PLASTIC			
2	NDC:52959-675-60	60 in 1 BOTTLE, PLASTIC			
3	NDC:52959-675-00	100 in 1 BOTTLE, PLASTIC			
4	NDC:52959-675-02	120 in 1 BOTTLE, PLASTIC			
5	NDC:52959-675-08	180 in 1 BOTTLE, PLASTIC			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/16/2011	

## Labeler - H.J. Harkins Company, Inc. (147681894)

# **Registrant -** RUGBY LABORATORIES, INC. (109178264)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
TIME-CAP LABS, INC		037052099	manufacture	

Revised: 12/2011 H.J. Harkins Company, Inc.