SENEXON-S- docusate sodium 50mg and sennosides 8.6mg tablet, film coated
RUGBY LABORATORIES

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.

Drug Facts

Active Ingredients (in each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool Softener

Laxative

Uses

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

Warnings

Do not use

- if you are now taking mineral oil, unless directed by a doctor
- laxative products for longer than 1 week 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 health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- 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

Other information

- each tablet contains: **calcium 10 mg, sodium 5 mg, Very Low Sodium**
- store at 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

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

Questions or comments?

1-800-645-2158

RUGBY

NDC 0536-1247-10

Compare to the active ingredients in Senokot-S®*

Senexon-S

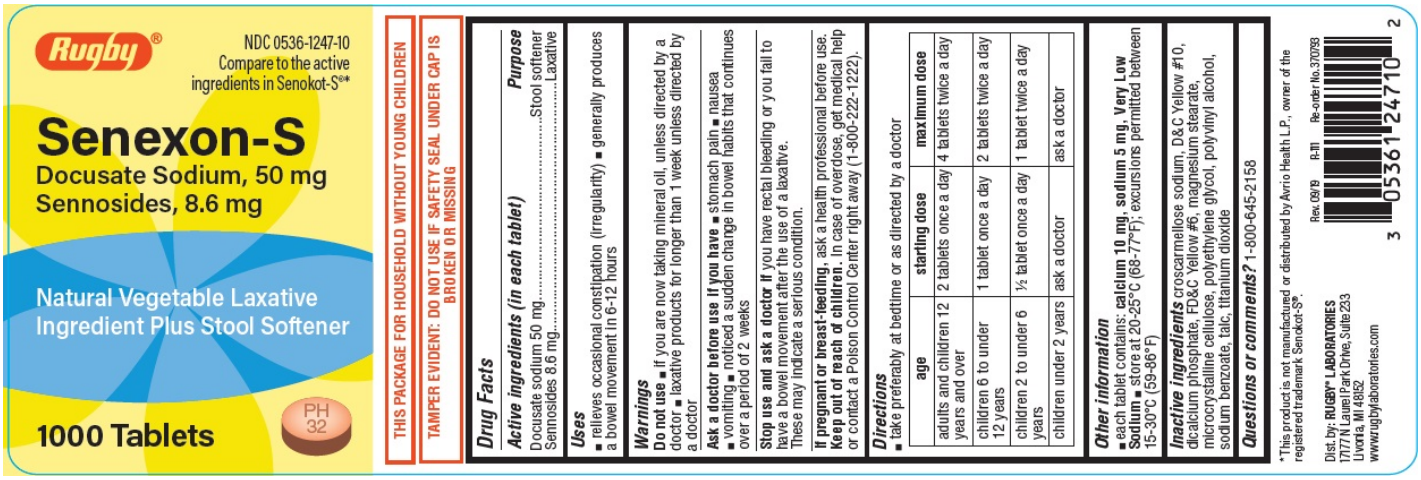
Docusate Sodium, 50 mg

Sennosides, 8.6 mg

Natural Vegetable Laxative

Ingredient Plus Stool Softener

1000 TABLETS



SENEXON-S

docusate sodium 50mg and sennosides 8.6mg tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1247
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:0536-1247-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/02/2019	
2	NDC:0536-1247-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/02/2019	

Labeler - RUGBY LABORATORIES (079246066)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(0536-1247) , analysis(0536-1247) , pack(0536-1247) , label(0536-1247)

Revised: 12/2022 RUGBY LABORATORIES