## SENNA-S- sennosides and docusate sodium tablet, film coated Kinray 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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#### **Drug Facts**

#### **Active Ingredients**

Sennosides from Senna Concentrate 8.6 mg Sodium Dioctylsulfosuccinate 50 mg

### **Purposes**

Sennosides from Senna Concentrate 8.6 mg......Laxative Sodium Dioctylsulfosuccinate 50 mg.....Stool Softener

#### Uses

- Relieves occasional constipation (irregularity)
- Generally produces a bowel movement in 6-12 hours.

#### **Warnings**

#### Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are now 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 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.

#### **Directions**

• take preferably at bedtime or as directed by a doctor

200	s tarting	maximum
age	dosage	dosage

adults and children 12	2 tablets	4 tablets	
years of age and over	once a day	twice a day	
children 6 to under 12	1 tablet	2 tablets	
years	once a day	twice a day	
children 2 to under 6 years		1 tablet	
children 2 to under o years	once a day	twice a day	
children under 2 years	ask a doctor	ask a doctor	

#### Other Information

- each tablet contains calcium 20 mg, sodium 6mg Low Sodium
- store at room temperature between 15-30 $^{\circ}$ C (59-86 $^{\circ}$ F)

## **Inactive ingredients**

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, tapoica starch, tartaric acid, titanium dioxide

Questions? Adverse drug event call: (866) 562-2756



Tamper Evident: Do not use if imprinted safety seal under cap is broken or missing.

#### Drug Facts

Active Ingredients (in each tablet)....Purpose Sennosides from Senna Concentrate 8.6 mg. .....Laxative

Sodium Dioctylsulfosuccinate 50 mg, ...Stool Softener

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

movement in 6-12 hours.

Warnings
Do not use laxative products for longer than 1 week unless directed by a doctor if you are now taking mineral oil, unless directed by a doctor. † This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot-S<sup>®</sup>.

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased

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 use of a laxative. These may indicate a sardus 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.

# 0 16103 36407 9 stributed By: Kinray, Inc., Whitestone, NY 11357

**60** Tablets (standard senna concentrate plus docusate sodium)

Gentle Natural Vegetable Laxative

Drug Facts (Continued)

<b>Directions take</b> preferably at bedtime or as directed by a doctor			
age	starting dosage	maximum dosage	
adults and children over 12 years	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 20mg, sodium 6 mg Low Sodium ■ store at room temperature between 15°-30°C (59°-86°F).

Inactive Ingredients Carnauba Wax, Colloidal Silicon Dioxide, Croscarmellose Sodium, Dicalcium Phosphate, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, Hypromellose, Magnesium Stearate, Microcrysta en Cellulose, Polyethylene Glycol, Sodium Benzoate, Stearic Acid, Tapioca Starch, Tartaric Acid, Titanium Dioxide.

Vegetable Laxative Gentle Natural

plus docusate sodium) (standard senna concentrate **Zeuus** 



Compare to the Active Ingredients in Senokot-S®1

**ν**εgetable Laxative Gentle Natural

plus docusate sodium) (standard senna concentrate

NDC 16103-0364-07

Compare to the Active Ingredients in Senokot-S®f

Vegetable Laxative Gentle Natural

plus docusate sodium) (standard senna concentrate

60 Tablets





**SENNA-S** 

sennosides and docusate sodium tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG NDC:61715-019 Item Code (Source)

**Route of Administration** ORAL

#### Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX)	SENNOSIDES	8.6 mg		
DO CUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
STARCH, TAPIO CA (UNII: 24SC3U704I)		
TARTARIC ACID (UNII: W4888I119H)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	orange (orange)	Score	no score	
Shape	ROUND (round shape)	Size	10 mm	
Flavor		Imprint Code	S90	
Contains				

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:61715-019-60	1 in 1 CARTON		
1		60 in 1 BOTTLE, PLASTIC		

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/10/2011	

## **Labeler -** Kinray Inc. (012574513)

## Registrant - Pharbest Pharmaceuticals Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceutical Inc.		557054835	repack(61715-019), relabel(61715-019)

Revised: 3/2013 Kinray Inc.