SENNA-S- sennosides 8.6mg and docusate sodium 50mg tablet, film coated Pharbest Pharmaceuticals, 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.

Drug Facts

Active Ingredients (in each tablet)

Sennosides from Senna Concentrate 8.6mg

Docusate Sodium 50mg

Purpose

Laxative

Stool Softner

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 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.

Directions

• take preferably at bedtime or as directed by a doctor

starting maximum

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

Other information

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

Inactive ingredients

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

Questions or comments?

(866) 562-2756 Mon-Fri 8 AM to 4 PM EST PHARBEST NDC 16103-378-07 Manufactured in the USA *Compare to the active ingredients in Senokot-S[®] SENNA-S Sennosides 8.6mg & Docusate Sodium 50mg Natural Vegetable Laxative Ingredient Plus Stool Softner 60 TABLETS



Facts (contd.) t a Poison Control Center iately.	do	e dosage dosage	2 over d	en 6 to 1 tablet 2 tablets 12 years once a twice a day day	2 to 1/2 tablet 1 tablet years once a twice a day day	under ask a ask a doctor	Other information = each tablet contains 10 mg of calcium, sodium 5 mg = store at 25° (77°F); excursions permitted between 15°-30°C (59°-86°F)	<i>Inactive ingredients</i> croscar- mellose sodium, D&C Yellow #10, dicalcium phosphate, FD&C Yellow #6, magnesium stearate, micro- crystalline cellulose, polyvinyl alcohol, polyethylene glycol, sodium benzoate, talc, titanium dioxide	Questions or comments? (866) 562-2756 Mon-Fri 8 AM to 4 PM EST	This product is not mendactured or distributed by Pudue Pharma L.P., owner of the neglescent tradement Sandor 35. STOP PEELING	
Drug Fact s contact a Po immediately.	Directions ■ take prefer directed by a	age	Adults and children 12 years and over	Children under 12	Children 2 to under 6 years	Children under 2 years	● ther = each t calcium 25° (77° betweer	Inactive mellose so dicalcium #6, magne crystalline alcohol, po benzoate,	Questi (866) 56 4 PM E	This product is 	

SENNA-S

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

Product Information					
Product Type	oduct TypeHUMAN OTC DRUGItem Code (Source)NDC				
Route of Administration	ORAL				
Active Ingredient/Active Moi	etv				
	gredient Name		Basis of S	trength	Strengtl
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX) SENNO SIDES					8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) DOCUSATE SODIUM				ODIUM	50 mg
Inactive Ingredients					
	Ingredient Name				Strength
CROSCARMELLOSE SODIUM (UNII:	M28OL1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5U	JSQ3G)				
CALCIUM PHO SPHATE, DIBASIC, D	HYDRATE (UNII: O7TSZ97GEP)	I			
FD&C YELLOW NO.6 (UNII: H77VEI	348)				

MAGNESIUM STEARATE (UNII: 70097M6B0)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
Product Characteristics	

Product Charact	erisucs
Color	orange (ORANGE COLOR)

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

P	ackaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:16103-378- 07	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/0 5/20 18		
2	NDC:16103-378- 11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/0 5/20 18		
3	NDC:16103-378- 08	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 2/2 1/20 19		
R					
I	Marketing Information				
	Marketing Categ	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

Marketing Category	Application Number of Monograph Citation	Marketing Start Date	Markeung Enu Date	I
OTC monograph not final	part334	11/05/2018		
				41

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-378), pack(16103-378), label(16103-378)	

Revised: 2/2019

Pharbest Pharmaceuticals, Inc.