SENNA PLUS- docusate sodium 50 mg and sennosides 8.6 mg tablet, film coated

CARDINAL HEALTH, 110 DBA LEADER

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 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?

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

LEADER TM

NDC 70000-0520-1

Senna Plus

Docusate Sodium, 50 mg

Sennosides, 8.6 mg

Stool Softener I Laxative

Dual Action

Standardized

Senna Concentrate

COMPARE TO

SENOKOT-S®

active ingredients*

100% Money

Back Guarantee

30 TABLETS



SENNA PLUS

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

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0520	
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: 3WJQ0SDW1A)			
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				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:70000- 0520-1	30 in 1 CARTON	10/23/2019	
	1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/23/2019	

Labeler - CARDINAL HEALTH, 110 DBA LEADER (063997360)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(70000-0520) , analysis(70000-0520) , pack(70000-0520) , label(70000-0520)

Revised: 6/2021 CARDINAL HEALTH, 110 DBA LEADER