PLUS PHARMA SENNA STANDARDIZED SENNA CONCENTRATE 8.6 MG SENNOSIDES EACH- sennosides tablet, film coated
Unit Dose Services

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 ingredient (in each tablet)

Sennosides 8.6 mg

Purpose

Laxative

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

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

age	starting dosage	maximum dosage
adults and children 12 years of age and older	2 tablets once a day	4 tablets twice a day

children 6 to under 12 years of age	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years of age	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 20 mg**
- Store at room temperature
- **Do not use if imprinted seal under cap is broken or missing**

Inactive ingredients

Calcium carbonate, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium sulfate, stearic acid, triacetin.

Questions?

If you have any questions or comments,or to report an adverse event, please contact (800) 795-9775.

PLUS PHARMA SENNA STANDARDIZED SENNA CONCENTRATE 8.6 MG SENNOSIDES EACH (SENNOSIDES) TABLET, FILM COATED

PLUS PHARMA SENNA STANDARDIZED SENNA CONCENTRATE 8.6 MG SENNOSIDES EACH

sennosides tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-5165(NDC:51645-851)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	brown	**Score**	2 pieces
Shape	ROUND (Biconvex)	**Size**	9mm
Flavor		**Imprint Code**	GPI;W2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-5165-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/27/2006	

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-5165)

Revised: 3/2006 Unit Dose Services