

SENNA- senna tablet, film coated
HIMPRIT PHARMACHEM PVT LTD

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.

SENNA TABLETS 8.6 mg

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 or older	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 25mg**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

croscarmellose sodium, dicalcium phosphate, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil

PRINCIPAL DISPLAY PANEL - Shipping Label

Each Film Coated Tablet Contains :

CALCIUM SENNOSIDES 8.6mg

Lot No. :

Mfg. Date :

Exp. Date :

Jar No. :

Quantity : 50,000 Tablets

NDC No : 65437 - 087 - 50

WARNING :

KEEP OUT OF THE REACH OF CHILDREN

STORE AT CONTROLLED ROOM TEMPERATURE OF 59°-77°F (15°-25° C)

PROTECT FROM LIGHT, MOISTURE AND FREEZING.

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT

CONFORMANCE WITH THE FDA AND REGULATIONS THEREUNDER.

Manufactured By :

MANUFACTURER CODE No.: Guj/Drugs/G/1362

LABELER CODE # 14803

Manufactured For.

HIMPRIT PHARMACHEM PVT. LTD.

"LAKULESH", R.V. DESAI ROAD,

NEXT TO NAVAPURA POLICE STATION,

BARODA, INDIA - 390 001

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

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SENNA

senna tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65437-087
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNA (UNII: AK7JF626KX) (SENNA - UNII:AK7JF626KX)	SENNA	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	BROWN	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	S8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-087-50	1 in 1 DRUM		
1		50000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part334	11/20/2009	

Labeler - HIMPRIT PHARMACHEM PVT LTD (917261992)**Registrant** - SPIRIT PHARMACEUTICALS,LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		858352983	MANUFACTURE

Revised: 11/2009

HIMPRIT PHARMACHEM PVT LTD