SENNA LEAF AND DOCUSATE SODIUM- senna leaf and docusate sodium 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 8.6mg & DOCUSATE SODIUM 50mg

Drug Facts

Active ingredients (in each tablet)	*Purpose*
Docusate sodium 50 mg	Stool softener
Sennosides 8.6 mg	Laxative

Uses

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

Warnings

Do not use

- if you are now 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 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

Inactive Ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, D&C Yellow

#10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, PEG 8000, sodium benzoate, stearic acid, tartaric acid, titanium dioxide

PRINCIPAL DISPLAY PANEL - Shipping Label

SENNA 8.6mg & DOCUSATE SODIUM 50mg
Orange Tablets
Each Tablet Contains:
CALCIUM SENNOSIDES 8.6mg
DOCUSATE SODIUM 50mg

Lot No:	Quantity:
Mfg Date:	Jar No:
Exp Date:	NDC NO: **65437-035-50**

WARNING:
KEEP OUT OF THE REACH OF CHILDREN

STORE AT CONTROLLED ROOM TEMPERATURE OF 59 - 77 F (15 - 25 C)
PROTECT FROM LIGHT,MOISURE 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 F.D. & C. ACT AND REGULATIONS THEREUNDER.

MANUFACTURED BY:
MANUFACTURED CODE NO Guj/Drugs/G/1362
LABELLER CODE # 14803

MANUFACTURED FOR:
HIMPRIT PHARMACHEM PVT.LTD.
"LAKULISH" R.V.DESAI ROAD
NEXT TO NAVAPURA POLICE STATION
BARODA, INDIA 390 001

SENNA 8.6mg & DOCUSATE SODIUM 50mg

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SENNA LEAF AND DOCUSATE SODIUM

senna leaf and docusate sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65437-035
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SENNA LEAF (UNII: AK7JF626KX) (SENNA LEAF - UNII:AK7JF626KX)	SENNA LEAF	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-035-50	1 in 1 DRUM		
1		50000 in 1 BAG		
2	NDC:65437-035-70	1 in 1 DRUM		
2		75000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	04/01/2010	

Labeler - HIMPRIT PHARMACHEM PVT LTD (917261992)

Revised: 3/2010 HIMPRIT PHARMACHEM PVT LTD