

**SENNALAX- sennosides a and b tablet, film coated
Bryant Ranch Prepack**

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.

Sennosides 8.6 mg

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 of age	ask a doctor	ask a doctor

Inactive ingredients

Acacia Gum, Calcium Carbonate, Croscarmellose Sodium, Dextrose, Hypromellose, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Propylene Glycol, Silicon Dioxide, Stearic Acid, Triacetin.

Questions?

Adverse Drug Event call (800) 616-2471

Sennosides 8.6mg Tablet

SENNALAX			
sennosides a and b tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63629-3207(NDC:0904-5165)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	8.6 mg
Inactive Ingredients			

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE (UNII: IY9XDZ35W2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B0)	
MALTO DEXTRIN (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:63629-3207-1	100 in 1 BOTTLE		
2	NDC:63629-3207-2	60 in 1 BOTTLE		
3	NDC:63629-3207-3	120 in 1 BOTTLE		
4	NDC:63629-3207-4	56 in 1 BOTTLE		
5	NDC:63629-3207-5	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/04/2011	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-3207) , RELABEL(63629-3207)