SENEXON - senna tablet, coated Aphena Pharma Solutions - Tennessee, LLC

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.

Active ingredient (in each tablet) Sennosides 8.6mg

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product tow or more hours before or after other drugs. Laxatives may affect how other drugs work.

Ask a doctor before use if you have noticed a sudden change in bowel habits that lasts over two weeks.

Do not use for longer than one week, when abdominal pain, nausea or vomiting are present.

Stop use and ask a doctor if: you have rectal bleeding; you fail to have a bowel movement after use of this product. These may indicate a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

uses

relieves occasional constipation(irregularity); generally causes bowel movement in 6-12 hours.

1800 645-2158 9 am - 5 pm Monday - Friday

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Inactive Ingredients croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, minerol oil

Dosage and Administration

Adults and children 12 years and over - 2 tablets once a day - maximum dosage - 4 tablets twice a day Children 6 to under 12 years - 1 tablet once a day maximum dosage - 2 tablets twice a day children 2 to under 6 years - 1/2 tablet once a day - maximum dosage - 1 tablet twice a day Relieves occasional constipation

Generally produces bowel movement in 6-12 hours

Repackaging Information

Please reference the *How Supplied* section listed above for a description of individual tablets. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	8.6 mg
100	71610-058-65

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20180514JH

PRINCIPAL DISPLAY PANEL - 8.6 mg

NDC 71610-058 - Sennosides (Senna) 8.6 mg



SENEXON

senna tablet, coated

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Pra	пист	Into	12111	

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-058(NDC:0536-5904)
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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			
Strength			

Product Characteristics			
Color	bro wn	Score	no score
Shape	ROUND	Size	9 m m
Flavor		Imprint Code	TCL080
Contains			

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1 NDC:71610-058	- 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2018		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/09/2006	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment			
Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-058)

Revised: 5/2018 Aphena Pharma Solutions - Tennessee, LLC