VALUMEDS NATURAL LAXATIVE- sennosides tablet, film coated Spirit Pharmaceuticals 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.

VALUMEDS NATURAL LAXATIVE

Drug Facts

Active ingredient (in each tablet)

Sennosides 8.6 mg

Purpose

Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces 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 lasts over 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

Age	Starting Dosage	Maximum Dosage
adults and children 12 years of	2 tablets once a	4 tablets twice a day
age or over	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 24 mg and sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, hypromellose, liquid paraffin, magnesium stearate, microcrystalline cellulose, maltodextrin, purified water, sodium lauryl sulphate, stearic acid

Questions or comments?

Call **1-888-333-9792**

Distributed By:

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL - 8.6 mg Tablet Bottle

VALUMEDS

*COMPARE TO THE ACTIVE

INGREDIENT IN **SENOKOT**®

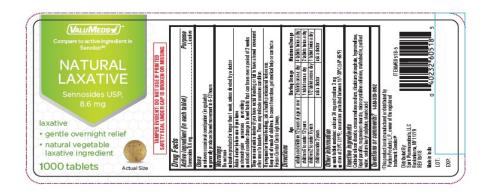
Natural Laxative

• Sennosides USP, 8.6 mg Laxative

Gentle, Overnight Relief Natural Vegetable Laxative Ingredient

Actual Size

100 TABLETS



VALUMEDS NATURAL LAXATIVE

sennosides tablet, film coated

Prod	1104	Info	uma	tion
P roa			пша	11011

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68210-0310

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients Ingredient Name Strength

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)

ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

MINERAL OIL (UNII: T5L8T28FGP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics				
Color	bro wn	Score	no score	
Shape	ROUND	Size	9mm	
Flavor		Imprint Code	S8	
Contains				

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0310-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2017	
2	NDC:68210-0310-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2017	
3	NDC:68210-0310-8	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/18/2017	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Establishment			
Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD.		863182240	manufacture(68210-0310)

Revised: 8/2019 Spirit Pharmaceuticals LLC