

LAXACIN- docusate sodium and sennosides tablet

Alexso, Inc.

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.

Laxacin

Laxative Plus Stool Softener

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

Purposes

Stool softener

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

adults and children 12

starting dose

2 tablets once a day

maximum dose

4 tablets twice a day

years and older

children 6 to under 12 years

children 2 to under 6 years

children under 2 years

1 tablet once a day

1/2 tablet once a day

ask a doctor

2 tablets twice a day

1 tablet twice a day

ask a doctor

Other information

- each tablet contains: **calcium 20 mg, sodium 4 mg**
- keep lid tightly closed
- store at room temperature in a dry place

Inactive ingredients Croscarmellose sodium, D&C yellow #10, dextrose, dicalcium phosphate, FD&C yellow #6, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silica, sodium benzoate, stearic acid, titanium dioxide.

Questions? If you have any questions or comments, or to report an adverse event, please contact **(800) 495-6078**

Manufactured for:

Alexso Inc.

Los Angeles, CA 90064

NDC: 50488-0901-1

Laxacin

(laxastimucin)

Laxative Plus Stool Softener

Standardized Senna Concentrate 8.6 mg and Docusate Sodium 50 mg Each

Fast, Dependable Relief

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).

100 Tablets

Drug Facts DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING. Active ingredients (in each tablet) Docusate Sodium 50 mg Stool softener Sennosides 8.6 mg Laxative Purposes 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. LOT# EXP. DATE:	NDC: 50488-0901-1 Laxacin (laxastimucin) Laxative Plus Stool Softener Standardized Senna Concentrate 8.6 mg and Docusate Sodium 50 mg Each Fast, Dependable Relief Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye). 100 Tablets	Drug Facts (continued) Directions • take preferably at bedtime or as directed by a doctor <table border="1"><thead><tr><th>age</th><th>starting dose</th><th>maximum dose</th></tr></thead><tbody><tr><td>adults and children 12 years and older</td><td>2 tablets once a day</td><td>4 tablets twice a day</td></tr><tr><td>children 6 to under 12 years</td><td>1 tablet once a day</td><td>2 tablets twice a day</td></tr><tr><td>children 2 to under 6 years</td><td>1/2 tablet once a day</td><td>1 tablet twice a day</td></tr><tr><td>children under 2 years</td><td>ask a doctor</td><td>ask a doctor</td></tr></tbody></table> Other information • each tablet contains: calcium 20 mg, sodium 4 mg • keep lid tightly closed • store at room temperature in a dry place Inactive ingredients Croscarmellose sodium, D&C yellow #10, dextrose, dicalcium phosphate, FD&C yellow #6, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silica, sodium benzoate, stearic acid, titanium dioxide. Questions? If you have any questions or comments, or to report an adverse event, please contact (800)495-6078	age	starting dose	maximum dose	adults and children 12 years and 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
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Rev. 09/18

LAXACIN

docusate sodium and sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-0901
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES A AND B (UNII: 1B5FP42EN) (SENNOSIDES A AND B - UNII:1B5FP42EN)	SENNOSIDES A AND B	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G55
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-0901-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/15/2018	

Labeler - Alexso, Inc. (963338061)

