

LAXACIN- docusate sodium and sennosides tablet
Advanced Rx Pharmacy of 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.

Laxacin 50mg/8.6mg Tablets

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	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

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**

Laxacin tablets are supplied as follows:

Bottles of 100 tablets NDC: 80425-0345-01

Manufactured for:

Alexso Inc.

Los Angeles, CA 90064

Distributed by:

Advanced Rx Pharmacy of Tennessee, LLC



#100
NDC: 80425-0345-01 Source NDC: 50488-0901-01
Lot: XXXXXXXXX Expires: 6/21/2023



LAXACIN 50MG/8.6MG TABLET #100
NDC: 80425-0345-01
Source NDC: 50488-0901-01
Lot: XXXXXXXXX Exp: 6/21/2023

ALEXSO INC
S/N: 000000158977

LAXACIN

docusate sodium and sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80425-0345(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: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE 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:80425-0345-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/19/2023	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
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Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0345)
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Revised: 6/2023

Advanced Rx Pharmacy of Tennessee, LLC