LAXACIN- laxacin tablet
DIRECT RX

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

Docusate Sodium 50 mg

Sennosides 8.6 mg

Stool Softener

Laxative

relieves occasional constipation irregularity
generally produces a bowel movement in 6-12 hours

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.

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

take preferably at bedtime or as directly 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

Other information

Each tablet contains: Calcium 20 mg
Each tablet contains: Sodium 4 mg
Store at room temperature
Keep lid tightly closed in a dry place
Do not use if imprinted safety seal under cap is broken or missing

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

Drug Facts

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.

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

ther information

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

nactive 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.

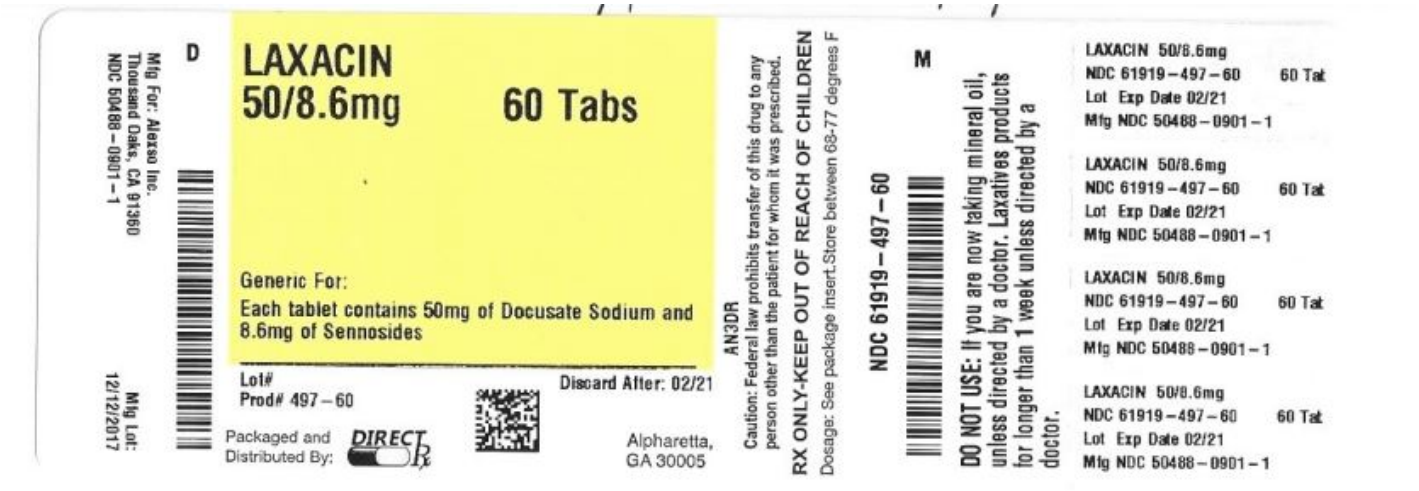
uestions? If you have any questions or comments, or to report an adverse event, please contact (800) 495-6078

Manufactured for:

Alexso Inc.

Los Angeles, CA 9006

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



[Laxacin 10-18]

LAXACIN

laxacin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-497(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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DEXTROSE (UNII: IY9XDZ35W2)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

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:61919-497-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/26/2018	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-497)

Revised: 3/2018 DIRECT RX