

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 | 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**

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) **Purposes**
Docusate Sodium 50 mg Stool softener
Sennosides 8.6 mg 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.

LOT#
EXP. DATE:

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100 Tablets

Drug Facts (continued)

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 | ½ 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.

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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: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN) | 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: 3WJQ05DW1A) | |
| 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)

Revised: 1/2022

Alexso, Inc.