SENNOSIDES, DOCUSATE SODIUM- sennosides, docusate sodium tablet, film coated Rugby Laboratories

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.

0490C-Rugby

Drug Facts

Active ingredients (in each tablet)

Sennosides 8.6 mg

Docusate sodium 50 mg

Purposes

Laxative

Stool softener

Uses

- relieves occasional constipation (irregularity)
- generally produces 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.

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 dosage | maximum dosage |
|---------------------------------------|----------------------|-----------------------|
| adults and children 12 years and over | 2 tablets once a day | 4 tablets twice a day |
| children 6 to under 12 years | 1 tablets once a day | 2 tablets twice a day |

Other information

■ each tablet contains: calcium 11 mg

■ each tablet contains: sodium 4 mg

■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

croscarmellose sodium, dicalcium phosphate, FD&C yellow #5 lake†, FD&C yellow #6 lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide and triacetin †contains FD&C yellow #5 lake (tartrazine) as a color additive.

Questions or comments?

1-800-645-2158

This is a bulk package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

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

*Rugby Laboratories is not affiliated with the owner of the registered trademark Senokot-S.®

Distributed by: Rugby Laboratories

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

www.rugbylaboratories.com

THIS PACKAGE IS FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Rugby ®

NDC 0536-1169-10

Senexon-S

NATURAL VEGETABLE INGREDIENT

STIMULANT LAXATIVE

PLUS STOOL SOFTENER

Docusate Sodium 50 mg

Sennosides 8.6 mg

1000 TABLETS

COMPARE TO THE ACTIVE INGREDIENTS IN SENOKOT-S®*





OOL SOFTENER des 8.6 mg e Sodium 50 mg L VEGETABLE

INGREDIENT

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| age | starting dosage | maximum dosage |
|---------------------------------------|-----------------------|-----------------------|
| adults and children 12 years and over | 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 | |

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Inactive ingredients croscamellose sodium, dicalcium phosphate, FD&C yellow #5 laket, FD&C yellow #6 lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide and triacetin toontains FD&C yellow #5 lake (tartrazine) as a color additive.

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12955-09-18 R-29 Rev. 09/18

Re-order No. 370592

Lot./ Exp. Date



SENNOSIDES, DOCUSATE SODIUM

sennosides, docusate sodium tablet, film coated

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:0536-1169

Route of Administration ORAL

Active Ingredient/Active Moiety

| 3 | | |
|---|---------------------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UN | NII:M7P27195AG) DOCUSATE SODIUM | 50 mg |
| SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP | P5M0 IJX) SENNO SIDES | 8.6 mg |

| | Ina | ctiv | e] | Ing | re | di | e | nt | S |
|--|-----|------|------------|-----|----|----|---|----|---|
|--|-----|------|------------|-----|----|----|---|----|---|

| Ingredient Name | Strength |
|--------------------------------------|----------|
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
|---|--|
| TALC (UNII: 7SEV7J4R1U) | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | |
| CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |

| Product Characteristics | | | | |
|-------------------------|---------|--------------|----------|--|
| Color | yello w | Score | no score | |
| Shape | ROUND | Size | 10 mm | |
| Flavor | | Imprint Code | CPC;490 | |
| Contains | | | | |

| l | Packaging | | | |
|---|--------------------|---|-----------------------------|---------------------------|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 NDC:0536-1169-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/17/20 18 | |
| | 2 NDC:0536-1169-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/13/2018 | |

| Marketing Inform | mation | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part334 | 12/13/20 18 | |
| | | | |

Labeler - Rugby Laboratories (079246066)

Revised: 5/2020 Rugby Laboratories