

MAXIMUM STRENGTH LAXATIVE- sennosides tablet, coated
CVS HEALTH

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.

195R-CVS MAXIMUM STRENGTH LAXATIVE

Each Tablet contains:

CALCIUM SENNOSIDES 25 mg

INACTIVE INGREDIENTS: acacia, calcium sulfate anhydrous, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue#1, iron oxide, iron oxide black, iron oxide yellow, kaolin, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, shellac, stearic acid, sugar, talc, titanium dioxide
stool softner, laxative

ses:

Relieves occasional constipation (irregularity); generally causes bowel movement in 6-12 hours

Directions:

Take preferably at bedtime or as directed by a doctor. If you do not have a comfortable bowel movement by the second day, increase dose by one tablet (not to exceed maximum dosage) or decrease dose until you are comfortable.

Adults and children 12 years and over - starting dosage: 2 tablets once a day maximum dosage: 4 tablets twice a day

Children 6 to under 12 years - starting dosage: 1 tablet once a day maximum dosage: 2 tablets twice a day

Children 6 to under 12 years - starting dosage: 1/2 tablet once a day maximum dosage: 1 tablet twice a day

Children under 2 years - Ask a doctor

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

WARNINGS:

Do not use this product

If you are presently taking mineral oil, unless directed by a doctor

Laxative products for longer than 1 week unless directed by a doctor

CVS Health. Compare to the active ingredient in ex-lax® Maximum Strength™
NDC 69842-195-25

MAXIMUM STRENGTH Laxative Pills
SENNOSIDES USP 25 mg

- Stimulant laxative
- Gentle, dependable
- Overnight relief

Actual Size

250 TABLETS

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet) Purpose
Sennosides USP, 25 mg Stimulant Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

Warnings

Do not use laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor

Ask a doctor before use if you have

- noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before use if you

- are taking any other drug. Laxatives may affect how other drugs work. Take this product 2 or more hours before or after other drugs.

When using this product

- do not use for a period longer than 1 week

Stop use and ask a doctor if

- rectal bleeding or failure to have a bowel movement occur after use of a laxative. These may be signs of a serious condition.

Drug Facts (continued under label)

*This product is not manufactured or distributed by Novartis owner of the registered trademark ex-lax®.
195R 0220

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CVS Pharmacy, Inc.
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CVS.com® #965887 0

V-37103 Lot No.:
PEE HERE Exp. Date:
UNVARNISHED AREA

MAXIMUM STRENGTH LAXATIVE

sennosides tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-195 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------|-------------------|----------|
| SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) | SENNOSIDES | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------------------------|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |

| |
|-----------------------------------------------------|
| KAOLIN (UNII: 24H4NWX5CO) |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) |
| CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H) |
| CARNAUBA WAX (UNII: R12CBM0EIZ) |
| MAGNESIUM STEARATE (UNII: 70097M6I30) |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| RAW SUGAR (UNII: 8M707QY5GH) |
| TALC (UNII: 7SEV7J4R1U) |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| STARCH, CORN (UNII: O8232NY3SJ) |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |
| POVIDONE (UNII: FZ989GH94E) |
| SHELLAC (UNII: 46N107B71O) |
| ACACIA (UNII: 5C5403N26O) |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | blue | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | TCL083 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:69842-195-24 | 24 in 1 BLISTER PACK; Type 0: Not a Combination Product | 12/01/2020 | |
| 2 | NDC:69842-195-09 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/01/2020 | |
| 3 | NDC:69842-195-25 | 250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part334 | 12/01/2020 | |

Labeler - CVS HEALTH (062312574)

Registrant - TIME CAP LABS,INC (037052099)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| TIME CAP LABORATORIES, INC. | | 037052099 | manufacture(69842-195) |

