

CITROMA- magnesium citrate liquid
OnPoint, 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.

Magnesium Citrate
693

Active ingredient

Magnesium citrate 1.745g per fl oz

Purpose

Saline laxative

Use

for relief of occasional constipation (irregularity). Generally produces bowel movement in 1/2 to 6 hours

WARNINGS

for this product

Ask A Doctor before use if you have

- kidney disease
- a magnesium or potassium restricted diet
- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks
- already used a laxative for a period longer than 1 week

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if

you have rectal bleeding or failure to have a bowel movement after use. These could be signs of 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

- drink a full glass (8 ounces) of liquid with each dose
- may be taken as a single daily dose or in divided doses

adults and children 12 years of age and over - 6.5 to 10 fl oz; maximum 10 fl oz in 24 hours

children 6 to under 12 years of age - 3 to 7 fl oz; maximum 7 fl oz in 24 hours

children 2 to under 6 years of age - 2 to 3 fl oz; maximum of 3 fl oz in 24 hours

children under 2 years of age - ask a doctor

discard unused product within 24 hours of opening bottle

Other information

- magnesium content 290 mg
- potassium content 80 mg
- store at temperatures between 46° and 86° F (8° and 30° C)

Inactive ingredients

cherry flavor, citric acid, potassium bicarbonate, purified water, red 40, sodium saccharin

DISTRIBUTED ABY ONPOINT, INC.

2 PARAGON DRIVE

MONTVALE, NJ 07645

693.001/693AD/AE

principal display panel

DO NOT USE IF TAMPER EVIDENT TWIST-OFF CAP IS MISSING, BROKEN OR SEPARATED FROM NECKRING

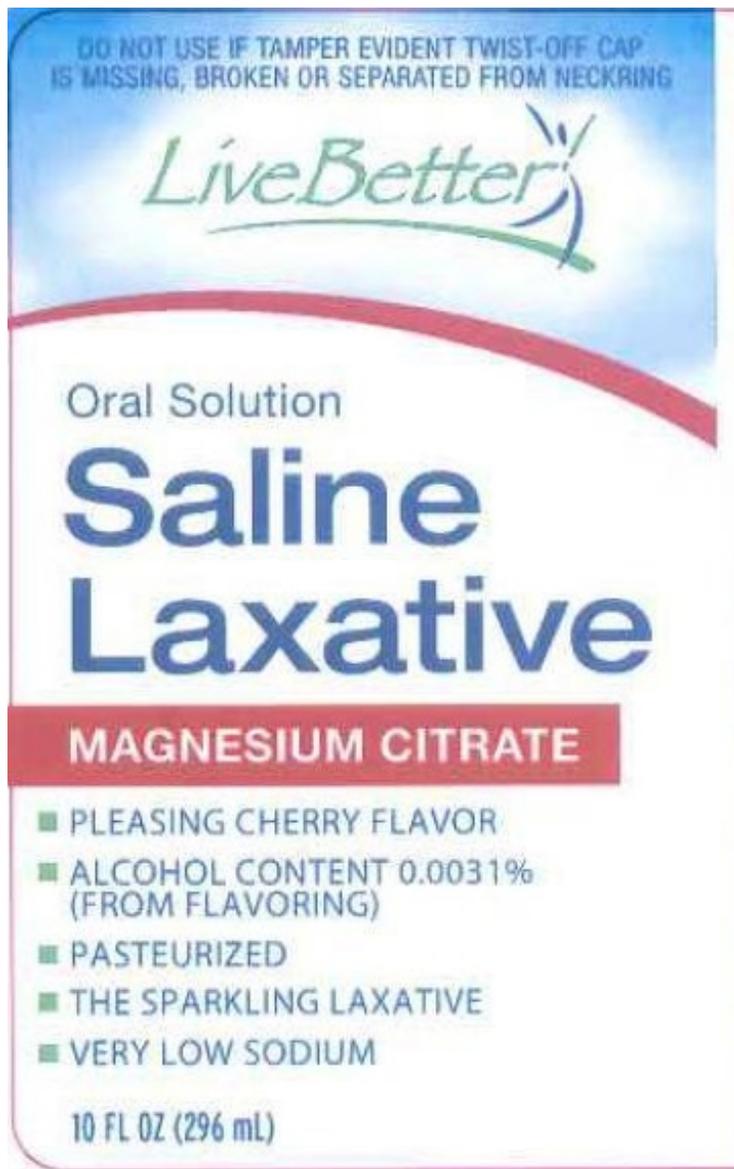
Live Better Oral solution

Saline Laxative

MAGNESIUM CITRATE

- PLEASING CHERRY FLAVOR
- ALCOHOL CONTENT 0.031% (FROM FLAVORING)
- PASTEURIZED
- THE SPARKLING LAXATIVE
- VERY LOW SODIUM

10 FL OZ (296 mL)



CITROMA

magnesium citrate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51143-693 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------------|
| MAGNESIUM CITRATE (UNII: RHO26O1T9V) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM CITRATE | 1.745 g in 29.6 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------|----------|
| CHERRY (UNII: BUC5I9595W) | |

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)

WATER (UNII: 059QF0KO0R)

FD&C RED NO. 40 (UNII: WZB9127XOA)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51143-693-38 | 296 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | 06/25/2009 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 06/25/2009 | |

Labeler - OnPoint, Inc (001367366)

Registrant - Vi-Jon (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Vi-Jon | | 790752542 | manufacture(51143-693) |

Revised: 5/2020

OnPoint, Inc