#### CITROMA- magnesium citrate liquid Major Pharmaceuticals

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.

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Magnesium Citrate 166

#### **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 restricted diet
- abdorominal 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 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

Store at temperatures between 46° and 86°F (8° and 30° C)

#### 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 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 in 24 hours children under 2 years of age - ask a doctor

#### other information

- each fl oz contains: magnesium 295 mg
- each fl oz contains: **sodium 1 mg**

#### **Inactive ingredients**

benzoic acid, citric acid, disodium EDTA, flavor, sucralose, water

#### Questions or comments?

(800)616-2471

#### principal display panel

MAJOR Magnesium Citrate Saline Laxative Lemon Flavored Alcohol content 0.012% from flavoring DO NOT UISE IF TAMPER EVIDENT TWIST-OFF CAP IS MISSING, BROKEN OR SEPARATED FROM NECKRING 10 FL OZ (296 mL)

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Magnesium Citrate Saline Laxative

Lemon flavored

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Alcohol content 0.012% from flavoring) DO NOT USE IF TAMPER EVIDENT TWIST-OFF CAP IS MISSING, BROKEN OR SEPARATED FROM NECKRING

## 10 FL OZ (296 mL)

magnesium citrate liquid

| Product Information                                                                                                 |                                         |                        |  |       |                       |  |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------|--|-------|-----------------------|--|
| Product Information                                                                                                 |                                         |                        |  |       |                       |  |
| Product Type                                                                                                        | HUMAN OTC DRUG                          | Item Code (Source) NDC |  | NDC:0 | 2:0904-6787           |  |
| Route of Administration                                                                                             | ORAL                                    |                        |  |       |                       |  |
|                                                                                                                     |                                         |                        |  |       |                       |  |
|                                                                                                                     |                                         |                        |  |       |                       |  |
| Active Ingredient/Active Mo                                                                                         | iety                                    |                        |  |       |                       |  |
| Ingredient Name Basis of Strength                                                                                   |                                         |                        |  |       | Strength              |  |
| MAGNESIUM CITRATE (UNII: RHO2                                                                                       | MAGNESIUM<br>CITRATE                    |                        |  |       |                       |  |
|                                                                                                                     | 50119 V) (MAGNESIUM CATION              | -                      |  |       | 1.745 g<br>in 29.6 mL |  |
|                                                                                                                     | 50119 V) (MAGNESIUM CATION              | -                      |  |       |                       |  |
|                                                                                                                     | 50119V) (MAGNESIUM CATION               | -                      |  |       |                       |  |
| UNII:T6V3LHY838)                                                                                                    | 50119V) (MAGNESIUM CATION               | -                      |  |       |                       |  |
| UNII:T6V3LHY838)                                                                                                    | Ingredient Name                         | -                      |  |       |                       |  |
| UNII:T6V3LHY838)<br>Inactive Ingredients                                                                            | Ingredient Name                         | -                      |  |       | in 29.6 mL            |  |
| UNII:T6V3LHY838)<br>Inactive Ingredients<br>BENZOIC ACID (UNII: 85KN0B0MIM                                          | Ingredient Name                         | -                      |  |       | in 29.6 mL            |  |
| Inactive Ingredients<br>BENZOIC ACID (UNII: 85KN0B0MIM<br>CITRIC ACID MONOHYDRATE (UN<br>EDETATE DISODIUM ANHYDROUS | Ingredient Name<br>D<br>II: 2968PHW8QP) | -                      |  |       | in 29.6 mL            |  |

water (UNII: 059QF0KO0R)

| Package Description                                            | Marketing Start<br>Date | Marketing End                                                                          |
|----------------------------------------------------------------|-------------------------|----------------------------------------------------------------------------------------|
|                                                                | -                       | U                                                                                      |
|                                                                |                         | Date                                                                                   |
| 296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/18/2018              |                                                                                        |
|                                                                |                         |                                                                                        |
| ormation                                                       |                         |                                                                                        |
|                                                                | Marketing Start Date    | Marketing End Date                                                                     |
| nal part334                                                    | 02/18/2018              |                                                                                        |
|                                                                |                         | Product   Cormation   ry Application Number or Monograph Citation Marketing Start Date |

Labeler - Major Pharmaceuticals (191427277)

Registrant - Vi-Jon, Inc (790752542)

### Establishment

| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Vi-Jon, Inc |         | 790752542 | manufacture(0904-6787) |

Revised: 5/2020

Major Pharmaceuticals