# MAGNESIUM CITRATE- magnesium citrate solution H E BUTT

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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# Cherry Magnesium Citrate 164.000/164AA rev 2-AB

#### **TEP**

Do Not Use If Tamper Evident Twist-off Cap Is Missing, Broken or Separated From Neckring

### **Active ingredient**

Active ingredient in each fl oz Magnesium citrate 1.745 g

### **Purpose**

Saline Laxative

#### Uses

- for relief of occasiona constipation (irregularity).
- Generally produces bowel movement in 1/2 to 6 house

# Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium 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

**If pregnant or breast-feeding,** ask a health professional before use.

#### Keep out of reach of children

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**

- shake well before using
- drink a full glass (8 ounces) of liquid each dose
- may be taken as a single dose or in a divided doses

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

childrem 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 3 fl oz in 24 hours children under 2 years of age- ask a doctor

#### other information

• each fl oz contains: magnesium 290 mg

• each fl oz contains: sodium 1 mg

## **Inactive ingredients**

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

#### Questions

Call? 1-888-593-0593

#### Adverse reactions

MADE WITH PRIDE & CARE FOR H-E-B SAN ANTONIO, TX 78204

# principal display panel

H-E-B

Magnesium Citrate

**Oral Solution** 

Saline Lazative

• Relief of: Occasional Constipation

Sugar & Dye Free

Gluten Free

Cherry Flavor

10 FL OZ (296 mL)



#### **MAGNESIUM CITRATE**

magnesium citrate solution

| <b>Product Information</b> |  |
|----------------------------|--|
|----------------------------|--|

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:37808-673

ORAL **Route of Administration** 

## **Active Ingredient/Active Moiety**

**Basis of Ingredient Name** Strength Strength

MAGNESIUM CITRATE (UNII: RHO2601T9V) (MAGNESIUM CATION -

UNII:T6V3LHY838)

MAGNESIUM CITRATE 0.059 g in 1 mL

# Inactive Ingredients

| mactive ingredients                           |          |  |
|---|----------|--|
| Ingredient Name                               | Strength |  |
| BENZOIC ACID (UNII: 85KN0B0MIM)               |          |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)    |          |  |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |          |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                  |          |  |
| water (UNII: 059QF0KO0R)                      |          |  |

#### **Packaging**

| ı | _ |                      |  |                         |                       |
|---|---|----------------------|--|-------------------------|-----------------------|
|   | # | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|   |   | NDC:37808-<br>673-38 | 296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/17/2021              |                       |

# Marketing Information

| Marketing               | Application Number or Monograph | Marketing Start | Marketing End |
|-------------------------|---------------------------------|-----------------|---------------|
| Category                | Citation                        | Date            | Date          |
| OTC monograph not final | part334                         | 08/17/2021      |               |

### **Labeler -** H E BUTT (007924756)

# Registrant - Vi-Jon, LLC (790752542)

## **Establishment**

| Name        | Address | ID/FEI    | <b>Business Operations</b> |
|-------------|---------|-----------|----------------------------|
| Vi-Jon, LLC |         | 790752542 | manufacture(37808-673)     |

| <b>Estab</b> | lish | ment |
|--------------|------|------|
|--------------|------|------|

| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC |         | 088520668 | manufacture(37808-673) |

Revised: 9/2022 H E BUTT