

CITROMA- magnesium citrate liquid
STRATEGIC SOURCING SERVICES LLC

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
164.000 164AA rev 2 -164AB

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
- 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 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 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 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

Adverse Reaction

Distributed By McKesson

One Post Street, San Francisco, CA 94104

Money Back Guarantee

principal display panel

sunmark

NDC 401677-0053-71

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

magnesium citrate Saline Laxative Oral Solution

Alcohol content 0.0205% (from flavoring)

Non-pasteurized

Saccharin free

Break resistant

Very low sodium

BPA free

CHERRY FLAVOR

Distributed By McKesson

One Post Street, San Francisco, CA 94104

Money Back Guarantee

10 FL OZ (296 mL)



CITROMA

magnesium citrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0053
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0053-1	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/18/2018	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(70677-0053)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(70677-0053)