

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
166.000/166AA rev 1 - 166AB

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 Steet, San Francisco, CA 94104

Money Back Guarantee

principal display panel

Sunmark

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

MAGNESIUM CITRATE

Saline Laxative

Oral Solution

Alcohol content 0.012% (from flavoring)
Non-pasteurized
Saccharin free
Break resistant
Very Low sodium
BPA free
LEMON FLAVOR
Disributed 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:70677-0051

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:70677-0051-1	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(70677-0051)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(70677-0051)