

CITROMA- magnesium citrate liquid
MIDWOOD BRANDS, 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.

Drug Facts Family Wellness 166.000/166AA rev 1

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

- shake well first
- 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 290 mg**
- each fl oz contains: **sodium 1 mg**

Inactive ingredients

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

TEP

TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

Adverse Reaction

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY

CHESAPEAKE, VA 23320

NOT 100% SATISFIED?

Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange

166.000/166AA rev 2

PRINCIPAL DISPLAY PANEL

FAMILY

Wellness

NDC 55319-666-38

Magnesium

Citrate

Saline laxative

Alcohol content 0.0125% (from flavoring)
LEMON
100% SATISFACTION GUARANTEED
OR YOUR MONEY BACK
10 FL OZ (295 mL)



CITROMA			
magnesium citrate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-666
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)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-666-38	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/18/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/18/2019	

Labeler - MIDWOOD BRANDS, LLC (024472631)

Registrant - Vi-Jon, Inc (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		790752542	manufacture(55319-666)