

CITROMA- magesium citrate liquid
Perrigo Direct, Inc.

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.

Cherry Magnesium Citrate
164.000/164AA rev 2-AB

Active Ingredient (in each fl oz)

Magnesium citrate 1.745g

Purpose

Saline laxative

Uses

- 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 tat 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 help 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 before using
- 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 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

Non-USP: Non-Carbonated, Non-Pasteurized; Contains Preservatives

Distributed By: Perrigo Direct, Inc.

Peachtree City, GA 30269

1-888-593-0593

www.PerrigoDirect.com

GoodSense is a registered trademark of L. Perrigo Company.

Principal Panel Display

NDC 50804-164-38

GOODSENSE

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

Magnesium

Citrate

Saline Laxative

Oral Solution

- Non-pasteurized
- Saccharin free

Cherry Flavor

10 FL OZ (296 mL)



CITROMA			
magesium citrate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-164
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:50804-164-38	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 - Perrigo Direct, Inc. (076059836)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(50804-164)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(50804-164)