CITROMA- magnesium citrate liquid OLD EAST MAIN CO

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.

Lemon Magnesium Citrate 166.000/166AA rev 1-166AB

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 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 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

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

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Principal display panel

Since 1903

Rexall

Magnesium

Citrate

Saline Laxative

- Oral Solution
- Relief of occasion constipation

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

Lemon Flavored

10 FL OZ (296 mL)



CITROMA

magnesium citrate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-183
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MAGNESIUM CITRATE (UNII: RHO2601T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	1.745 g in 29.6 mL

Inactive 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			
# Item Code	le Package Description Marketing Start Mark		Marketing End Date
NDC:55910- 183-38	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/04/2019	

Labeler - OLD EAST MAIN CO (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(55910-183)	

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-183)

Revised: 3/2023 OLD EAST MAIN CO