CITROMA- magnesium citrate liquid Foodhold U.S.A., 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

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 betweem 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 ozmaximum 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

DISTRIBUTED BY: FOODHOLD U.S.A., LLC, LANDOVER, MD 20785

For product questions or concers, contact us at 1-877-846-9949

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164.000/164AA rev 2

principal display panel

CAREONE

MAGNESIUM CITRATE

Saline Laxative

Cherry Flavor

ALCOHOL CONTENT 0.0250%

(FROM FLAVORING)

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

OUR PHARMACISTS RECOMMENDED

10 FL OZ (296 mL)



CITROMA

magnesium citrate liquid

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-725
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Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MAGNESIUM CITRATE (UNII: RHO26O1T9V) (MAGNESIUM CATION UNII:T6V3LHY838) MAGNESIUM CITRATE in 29.6 mL

Inactive Ingredients			
Ingredient Name	Strength		
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
water (UNII: 059QF0KO0R)			

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:41520-725- 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 - Foodhold U.S.A., LLC (809183973)

Registrant - Vi-Jon, Inc (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, Inc		790752542	manufacture(41520-725)	

Revised: 5/2020 Foodhold U.S.A., LLC