

CITROMA- magnesium citrate liquid

Harris Teeter, 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

Active ingredient

Magnesium citrate 1.745 g 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 or potassium-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 serious condition.

If pregnant or breast-feeding

Ask a 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.

Directions

- drink a full glass (8 ounces) of liquid with each dose
- may be taken as a single dose or in divided doses

Adults and children 12 years 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

discard unused product within 24 hours of opening bottle

Other information

- each fl oz contains: magnesium 290 mg
- each fl oz contains: potassium 80 mg
- store at temperatures between 46° and 86° F (8° and 30° C)

inactive ingredients

citric acid, lemon oil, potassium bicarbonate, water purified, sodium saccharin

Questions?

Call 1-888-593-0593

Adverse reactions

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HARRIS TEETER, LLC, MATTHEWS, NC 28105

your plus guarantee

1-800-432-6111 or harristeeter.com

686.001/686AD-AF

principal display panel

Harris Teeter

Magnesium

Citrate

Oral Solution

Saline Laxative

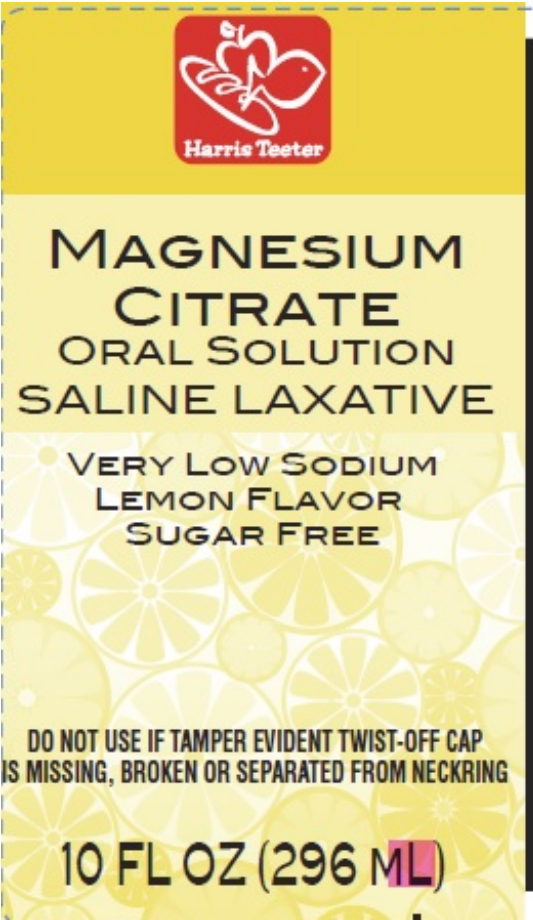
Very Low Sodium

Lemon Flavor

Sugar Free

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

10 FL OZ 296 mL)



CITROMA

magesium citrate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-686
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 29.61 mL
Inactive Ingredients			
Ingredient Name			Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
LEMON OIL (UNII: I9GRO824LL)			
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)			
water (UNII: 059QF0K00R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72036-686-38	296 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	05/03/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part334	05/03/2017	

Labeler - Harris Teeter, LLC (047279351)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(72036-686)