CITROMA- magnesium citrate liquid Major Pharmaceuticals

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

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Magnesium citrate 1.745g per fl oz

Purpose

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Saline laxative

use

Use for relief of occasional constipation (irregularity). Generally produces bowel movement in 1/2 to 6 hours

Warnings

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Do not use

Do not use if you are on a low salt diet

Ask A Doctor

Ask a doctor before use if you have

- kidney disease
- a magnesium or sodium restricted diet
- abdorominal 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

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

Stop use and ask a doctor if you have rectal bleeding or failure to have a bowel movement afte use. These could be signs of a serious condition.

if pregnant or breast-feeding

If pregnant or breast-feeding, ask help professional before use.

Keep out of reach of children.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Directions

Directions

- 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 children under 2 years of age - ask a doctor discard unused product within 24 hours of opening bottle

other information

Other information

- magnesium content 290 mg per 1 fl oz (30 mL)
- sodium content 45mg per 1 fl oz (30 mL)
- store at temperatures between 46° and 86° F (8° and 30° C)

Inactive ingredients

Inactive ingredients citric acid, lemon oil, polyethylene glycol, purified water, sodium bicarbonate, sodium saccharin, sucrose

Questions

Questions or Comments? 1-800-616-2471

Adverse Reaction

Distributed By: MAJOR PHARMACEUTICALS 31778 Enterprise Drive Livonia, MI 48150 USA

Principal display panel

NDC 0904-6304-77

MAJOR

Magnesium Citrate

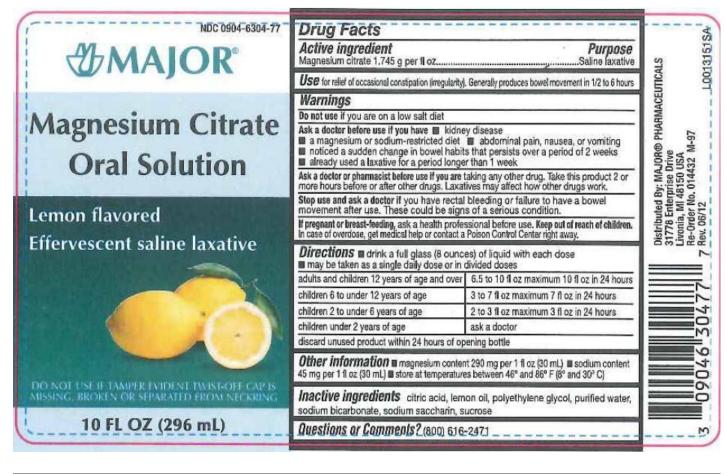
Oral solution

Lemon flavored

Effervescent saline laxative

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

Drad	luct	Information
Proa	HICT	Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:0904-6304

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthMAGNESIUM CITRATE (MAGNESIUM CATION)MAGNESIUM CITRATE1.745 g in 29.6 mL

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inactive ingredients			
Ingredient Name	Strength		
CITRIC ACID MO NO HYDRATE			
LEMONOIL			
PO TASSIUM BICARBONATE			

SACCHARIN SODIUM WATER

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0904-6304-77	296 mL in 1 BOTTLE, GLASS		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part334	08/27/2012		

Labeler - Major Pharmaceuticals (191427277)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture(0904-6304)	

Revised: 3/2013 Major Pharmaceuticals