CITROMA- magnesium citrate liquid Western Family Foods, 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.

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

Do not use

• if you are on a low salt diet

Ask a doctor

before use if you have

- kidney disease
- a magnesium or sodium-restricted diet
- abdominal pain, nausea or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks
- already use a laxative for a period longer than 1 week

Ask a doctor or pharmacist before use if you are

taking any other drugs. 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 moverment after use. These could be signs of a 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 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 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

Other information

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

Inactive ingredients

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

Questions or comments

1-800-525-2558

Adverse Reactions

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Principal Display Panel

WESTERN

FAMILY

Magnesium

Citrate

Saline Laxatixe

Oral Solution

TAMPER EVIDENT:

DO NOT USE IF THE BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

10 FL OZ (296 mL)



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 ½ to 6 hours

Warnings

Do not use

if you are on a low salt diet

Ask a doctor before use if you have

- kidney disease a magnesium or sodium-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 a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a

Drug Facts (continued)

Poison Control Center right away.

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 maximum 10 fl oz in 24 hours
children 6 to under 12	3 to 7 fl oz maximum
years of age	7 fl oz in 24 hours
children 2 to under 6	2 to 3 fl oz maximum
years of age	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

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

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

Questions? call 1-800-525-2558

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CITROMA

magnesium citrate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55312-667

Route of Administration ORAL

Active Ingredient/Active Moiety

ı	Active ingredient/Active wrotety					
	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 MO NO HYDRATE (UNII: 2968 PHW8 QP) LEMON OIL (UNII: 19 GRO 8 24 LL) POLYETHYLENE GLYCOLS (UNII: 3WJQ0 SDW1A) WATER (UNII: 059 QF0 KO0 R) SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO) SACCHARIN SODIUM (UNII: SB8 ZUX40 TY) SUCRO SE (UNII: C151 H8 M554)

Packaging					
#	Item Code	Package Description	Marketi	ng Start Date	Marketing End Date
1 NDC:	55312-667-38	296 mL in 1 BOTTLE, GLASS			
Marketing Information					
Mark	eting Category	Application Number or Monograp	h Citation	Marketing Start Dat	e Marketing End Date
OTC mo	nograph not final	part334		04/15/1990	

Labeler - Western Family Foods, Inc (192166072)

Registrant - Vi-Jon (790752542)

Establishment						
Name	Address	ID/FEI	Business Operations			
Vi-Jon		790752542	manufacture(55312-667)			

Revised: 11/2014 Western Family Foods, Inc