

CITROMA- magnesium citrate liquid

Vi Jon, 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

Purpose

Saline laxative

Use

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

Warnings

for this product

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

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 Poison Control Center right away
store at temperatures between 46° and 86°F (8° and 30° C)

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 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: **sodium 45 mg**

Inactive ingredients

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

Adverse reactions section

Distributed by:

Vi-Jon

One Swan Drive

Smyrna, TN 37167

667.001/667AG

Principal display panel

NDC 0869-0667-38

SWAN

Citroma

MAGNESIUM CITRATE

lemony

- Oral Solution
- Saline Laxative
- Pasturized
- The sparkling Laxative

Do not use if tamper evident tist-off cap is missing, broken or separated from neckring

10 FL OZ (296 mL)

NDC 0869-0667-38



lemony

- Oral Solution
- Saline Laxative
- Pasteurized
- The Sparkling Laxative



Do not use if tamper evident twist-off cap is missing, broken or separated from necking

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 (regularity). Generally produces bowel movement in 12 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, abdominal pain, nausea, or vomiting, noticed a sudden change in bowel habits that persists over a period of two 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. 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 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 ■ 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, sodium bicarbonate, sodium saccharin, sucrose, water purified

Distributed by:
Vijon
One Swan Drive
Smyrna, TN 37167
L00030745B



CITROMA

magnesium citrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0667
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 29.6 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LEMON OIL (UNII: I9GRO824LL)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
water (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0667-38	296 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	07/15/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/15/1989	

Labeler - Vi Jon, Inc (790752542)**Registrant** - Vi Jon, Inc (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi Jon Inc		790752542	manufacture(0869-0667)

Revised: 5/2019

Vi Jon, Inc