MAGNESIUM CITRATE- magnesium citrate solution Cardinal Health

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.

Cherry Magnesium Citrate 164.000/164AA rev 1-ab

Active ingredient

Active ingredient in each fl oz Magnesium citrate 1.745 g

Purpose

Saline Laxative

Uses

- for relief of occasiona constipation (irregularity).
- Generally produces bowel movement in 1/2 to 6 house

Warnings

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

If pregnant or breast-feeding, ask a health 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.

Store at temperatures between 46° and 86°F (8° and 30°C)

Directions

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

adults and children 12 years of age and over - 6.5 - 10 fl oz maximum 10 fl oz in 24 hours

childrem 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

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

Adverse reactions

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 www.myleader.com

1-800-200-6313

principal display panel

LEADER

NDC 70000-0575-1

Sugar-Free

Magnesium Citrate

Saline Laxative

Cherry

Flavor

Non-Pasterurzed

Break Resistant

BPA-Free

100% Money Back Guarantee

10 FL OZ (296 mL)



Route of Administration

MAGNESIUM CITRATE magnesium citrate solution Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0575

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MAGNESIUM CITRATE (UNII: RHO2601T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	0.059 g in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BENZOIC ACID (UNII: 85KN0B0MIM)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
water (UNII: 059QF0KO0R)			

ı	Packaging			
4	# Item Code Package Description		Marketing Start Marketing E Date Date	
1	NDC:70000- 0575-1	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/10/2021	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/10/2021	

Labeler - Cardinal Health (063997360)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(70000-0575)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(70000-0575)

Revised: 9/2022 Cardinal Health