MAGNESIUM CITRATE- magnesium citrate solution H E Butt

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.

Lemon Magnesium Citrate 166.000/166AA rev 1-AB

Active ingredient

Active ingredient (in each floz)

Magnesium citrate 1.745 g

purpose

Saline Laxative

Uses

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

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 durgs 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. Store at temperature between 46° and 86°F (8° abd 30°C)

Directions

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

Questions

Call 1-88-593-0593

Adverse reaction

MADE WITH PRIDE & CARE FOR H-E-B SAN ANTONIO, TN 78204

Principal Panel Display

H-E-B

Magnesium Citrate

Oral solution

saline Laxative

• Relief of: Occasion Constipation

Sugar & dye free

Gluten Free

Lemon Flavor

10 FL OZ (296 mL)

Do Not Use If Tamper Evident Twist-off Cap Is Missing, Broken or Separated From Neckring



MAGNESIUM CITRATE

magnesium citrate solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-769	
Route of Administration	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)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808- 769-38	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/07/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/07/2021	

Labeler - H E Butt (007924756)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37808-769)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37808-769)

Revised: 9/2022 H E Butt