MAGNESIUM CITRATE- magnesium citrate liquid Freds 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 1.745g per fl. oz.

Purpose

Saline laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 1/2 to 6 hours

Warnings

Do not use

laxative products for longer than 1 week unless directed by a doctor.

Ask a doctor before use if you have

- kidney disease
- a magnesium restricted diet
- a sodium restricted diet
- stomach pain, nausea or vomiting
- noticed a sudden change in bowel habits that lasts more than 1 week

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug.

When using this product

do not exceed the maximum recommended daily dosage in a 24 hour period

Stop use and ask a doctor if

you have rectal bleeding or no 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 (1-800-222-1222) right away.

Directions

years of age and older	1/2 to 1 bottle (10 fl. oz.). Drink a full 8 oz. glass of liquid with each dose. The dose may be taken as a single daily dose or in divided doses.
children 6 to 11 years of age	1/3 to 1/2 bottle with a full 8 oz. glass of liquid
children under 6 years of age	consult a doctor

Other information

- each fluid ounce contains: magnesium 282 mg, sodium 37 mg
- store between 46-86°F (8-30°F). Do not refrigerate
- protect from excessive heat and freezing
- discard unused product within 24 hours of opening bottles

Inactive ingredients

citric acid, FD&C blue #1, FD&C red #40, flavors, purified water, saccharin sodium, sodium bicarbonate

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-PM EST

Principal Display Panel

Magnesium Citrate

saline laxative

oral solution

Grape Flavor

FL OZ (mL)

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

DISTRIBUTED BY: fred's Inc

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Package Label



Fred's Magnesium Citrate Grape

MAGNESIUM CITRATE

magnesium citrate liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55315-328 **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	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
WATER (UNII: 059QF0KO0R)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		

Product Characteristics			
Color		Score	
Shape		Size	

Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:55315-328- 10	296 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/30/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	06/30/2015	

Labeler - Freds Inc (005866116)

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