

GADAVYT - magnesium citrate liquid
Gadal Laboratories 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 **Purpose**
Magnesium citrate 1.745g per fl. Oz..... Saline Laxative

Uses

- relieves 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
- 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
- you need to use a laxative for more than 1 week

Keep this and all drugs out of the reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center (1-800-222-1222) immediately

If pregnant or breast-feeding ask a health professional before use.

Directions

adults and children 12 years of age and older	1/2 to 1 bottle (10 fl. oz.) Drink a full 8 oz glass of liquid with each dose. These dose may be taken as a single daily dose or in divided doses
children 6 to under 12 years of age	1/3 to 1/2 bottle with a fill 8 oz glass of liquid
children under 6 years of age	consult a doctor

Other information

- each fluid ounce contains: sodium 36 mg, magnesium 199 mg

- store at room temperature
- protect from excessive heat and freezing
- discard unused product within 24 hours of opening

Inactive ingredients

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

Questions or comments?

(305) 382-3288

Gadal Laboratories Inc

Miami Fl 33186

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Manufactured by:
GADAL
Laboratories, Inc.
Miami, FL 33186



MADE IN THE USA



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GADAVYT

magnesium citrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM CITRATE (UNII: RHO26O1T9 V) (MAGNESIUM CATION - UNII:T6 V3LHY838)	MAGNESIUM CITRATE	1.745 g in 29.6 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (Grape)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-102-10	296 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part334	10/01/2012	

Labeler - Gadal Laboratories Inc (841305639)

Revised: 10/2012

Gadal Laboratories Inc