## 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.

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## **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**

	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 once 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

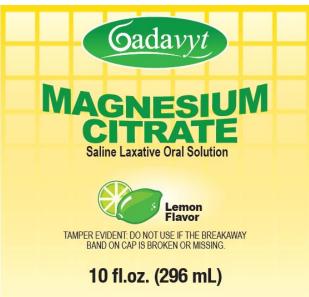
## Questions or comments?

(305) 382-3288

Gadal Laboratories Inc

Miami Fl 33186





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#### **GADAVYT**

magnesium citrate liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-103	
Route of Administration	ORAL			

ı	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	<b>MAGNESIUM CITRATE</b> (UNII: RHO26O1T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	1.745 g in 29.6 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
SACCHARIN SO DIUM DIHYDRATE (UNII: SB8ZUX40TY)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	LEMON (Lemon)	Imprint Code	
Contains			

	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
П	1 NDC:53113-103-10	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