MAGNESIUM CITRATE- magnesium citrate liquid NuCare Pharmaceuticals, 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.

Sunmark Magnesium Citrate

Active ingredient

Magnesium citrate 1.745 g per fl oz

Purpose

Saline laxative

Use 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 or potassium-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 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.

Directions • drink a full glass (8 ounces) of liquid with each dose

 may be taken as a single daily dose or in divided doses adults and children 12 years of age and over - 6.5 to 10 fl oz maximum 10 fl oz in 24 hours

children 6 to under 12 years of age - 3 to 7 fl oz maximum 7 fl oz in 25 hours children 2 to 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 discard unused product within 24 hours of opening bottle

Other information

- •magnesium content 290 mg per 1 fl oz (30 mL)
- •potassium content 80 mg per 1 fl oz (30 mL)
- •store at temperaturs between 46° and 86° F (8° and 30° C)

Inactive ingredients cherry flavor, citric acid, FD+C red # 40, potassium bicarbonate, sodium saccharin, water purified



NDC: 68071-4128-01 MFR NDC: 49348-504-49 Exp.: 00-00

Serial# 00000000001

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Call your doctor for medical advice about side effects. You may report side effects to FDA at

STORE AT CONTROLLED TEMPERATURE 59-86°F.

MAGNESIUM CITRATE

magnesium citrate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-4128(NDC:49348-504)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength	
MAGNESIUM CITRATE (UNII: RHO2601T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	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)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071- 4128-1	0.296 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/25/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	03/01/2002		

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment				
Name	Address	ID/FEI	Business Operations	
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-4128)	

Revised: 2/2022 NuCare Pharmaceuticals,Inc.