

**EPSOM SALT- magnesium sulfate granule, for solution**  
**Old East Main, CO**

*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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**Epsom Salt**  
**602.002-602AA**

**Active ingredient**

Magnesium sulfate USP (heptahydrate) 100%

**Purpose**

Saline Laxative

**Use**

- for relief of occasional constipation (irregularity)
- for this product 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 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**

### **Directions**

- do not exceed recommended daily dosage
- drink a full glass (8 ounces) of liquid with each dose
- may be taken as a single daily dose or in divided doses
- dissolve the dose in 8 ounces of water. Lemon juice may be added to improve the taste

adults and children 12 years and over - 2 to 6 level teaspoons (10 to 30 grams) daily

children 6 to under 12 years - 1 to 2 level teaspoons (5 to 10 grams) daily

children under 6 years - consult a doctor

## **Inactive Ingredients**

None

## **Other information**

- magnesium content 495 mg per teaspoon (5 grams)

## **Tamper Evident Packaging**

**Caution this package has been sealed for your protection. Do not use if package is open, torn or mutilated.**

**DIRECTIONS:** Dissolve 2 cupfuls of this product per gallon of water. Apply with bandages or toweling for 30 minutes up to three times a day or use as a soak or in bath. Use warm water for best results.

**Caution: if prompt relief is not obtained or there is evidence of infection, discontinue use and consult your physician. Hot or warm soaks should not be used by individuals with diabetes except on the advice of a physician. Keep out of reach of children.**

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**principal panel display**

## ZIPPER PLACEMENT

Since 1903 Rexall

Epsom Salt

Magnesium Sulfate U.S.P.  $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$

- Saline Laxative
- Soaking Aid - for minor sprains and bruises

NET WT 16 OZ

(1 LB) 454 g



# EPSOM SALT

magnesium sulfate granule, for solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-038
<b>Route of Administration</b>	ORAL, TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MAGNESIUM SULFATE HEPTAHYDRATE</b> (UNII: SK47B8698T) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE HEPTAHYDRATE	1 g in 1 g

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-038-43	453 g in 1 POUCH; Type 0: Not a Combination Product	10/21/1993	
2	NDC:55910-038-07	1814 g in 1 POUCH; Type 0: Not a Combination Product	10/21/1993	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/21/1993	

**Labeler** - Old East Main, CO (068331990)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-038)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-038)