

EPSOM SALT- magnesium sulfate granule, for solution
Wakefern Food Corp

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.

Epsom Salt
602.002/62AA

Active ingredient

Magnesium sulfate USP (Heptahydrate) 100%

Purpose

Saline laxative

Uses

- for relief of occasional constipation (irregularity)
- 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

- 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)

Discover the relaxing spa like qualities of this product in your bath

For Minor Sprains and Bruises

Saline Laxative

For Relief of Occasional Constipation

For external use as a soaking aid for minor sprain and bruises.

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 towelling for 30 minutes up to three times a day. For a less intensive soak, use 1 or 2 cupfuls 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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KEASBEY, NJ 08832

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epsom salt

Magnesium Sulfate U.S.P.

MgSO₄ 7H₂O

Saline Laxative

SOAKING AID

For Minor Sprains and Bruises

Net Wt 4 LB (1.81 kg)



EPSOM SALT

magnesium sulfate granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-602
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE HEPTAHYDRATE (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:41190-602-07	1814 g in 1 POUCH; Type 0: Not a Combination Product	05/01/2014	
2	NDC:41190-602-43	454 g in 1 POUCH; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/01/2014	

Labeler - Wakefern Food Corp (069722418)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41190-602)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41190-602)

Revised: 12/2022

Wakefern Food Corp