

EPSOM SALT- magnesium sulfate crystal
Cardinal Health, 110 dba Leader

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.

Leader Epsom Salt 602.002/602AA

SAFETY SEAL

TAMPER EVIDENT PACKAGING:

CAUTION: THIS PACKAGE HAS BEEN SEALED FOR YOUR PROTECTION.

DO NOT USE IF PACKAGE IS OPEN, TORN OR MUTILATED

Active ingredient

Magnesium sulfate USP (heptahydrate)100%

Purpose

Saline Laxative

Uses

Uses for Oral Laxative

- 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

Other information

- each teaspoon (5 grams) contains: magnesium 495 mg

claims

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

Directions: {For a relaxing bath/soak,} generously {or liberally} sprinkle {or pour} LEADER Epsom Salt into warm, running bath water

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.

Inactive Ingredients

None

Question and comments?

1-800-593-0593

Adverse reactions section

Cardinal Health

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CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1800-200-6313

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ALL LEADER Brand Product Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied

CIN 5516083 REV 4/19

principal display panel

CUT ALONG DOTTED LINE AND PRESS ZIPPER TO RESEAL

LEADER

NDC 70000-0021-1

EPSOM

SALT

Magnesium Sulfate USP, 100%

Saline Laxative

Saine Laxative

For Relief of Occasional

Constipation

Soaking Aid

For Minor Sprains

and Bruises

100% Money

Back Guarantee

Net WT 1 LB (454 g)



EPSOM SALT

magnesium sulfate crystal

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0021
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:70000-0021-2	1814 g in 1 POUCH; Type 0: Not a Combination Product	03/26/2012	
2	NDC:70000-0021-1	454 g in 1 POUCH; Type 0: Not a Combination Product	03/26/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/26/2012	

Labeler - Cardinal Health, 110 dba Leader (063997360)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(70000-0021)

Revised: 11/2022

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