EPSOM SALT- magnesium sulfate granule, for solution Liberty Procurement, 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.

Core Values 602.002/602AA Epsom Salt

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

Inactive Ingredient

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.

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

Directions: Dissolve 2 cupfuls of Core Values Epsom Salt per gallon of water. Apply with bandages or towelling 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.

Distributed by

Liberty Procurement, Inc.

Union, NJ 07083 USA

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RESEALABLE

Helps keep moisture out!

CORE VALUES EPSOM SALT

Magnesium Sulfate U.S.P.

MgSO4 7H20

- Saline Laxative for relief of occasional constipation
- Soaking Aid for minor sprains & bruises

Discover the relaxing spa-like qualities of Epsom Salt in your bath!

NET WT 6 LB (2.72kg)



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EPSOM SALT

magnesium sulfate granule, for solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63940-602

Route of Administration ORAL, TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM MAGNESIUM SULFATE

HEPTAHYDRATE

1 g in 1 g

CATION - UNII:T6V3LHY838)

HEPTAHYDRATE

Packaging								
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1	NDC:63940-602- 01	1814 g in 1 POUCH; Type 0: Not a Combination Product	07/11/2016				
	2	NDC:63940-602- 04	2721 g in 1 POUCH; Type 0: Not a Combination Product	07/11/2016				

MarketingApplication Number or MonographMarketing StartMarketing EndCategoryCitationDateDate

OTC monograph not final	part334	07/11/2016	

Labeler - Liberty Procurement, Inc (804085293)

Registrant - Vi-Jon, LLC (790752542)

Establishment							
Name	Address	ID/FEI	Business Operations				
Vi-Jon, LLC		790752542	manufacture(63940-602)				

Revised: 9/2023 Liberty Procurement, Inc