EPSOM SALT- magnesium sulfate granule, for solution Safeway 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.

Epsom Salt 602.002/602AA

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

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)

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 this product 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.

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Epsom Salt

Magnesium Sulfate U.S.P.

MgSO4 + 7H20

Soaking aid for minor sprains & bruises

Saline laxative for relief of occasional constipation

NET WT 16 OZ (1 LB) 454 g



EPSOM SALT

magnesium sulfate granule, for solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-602
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	MAGNESIUM SULFATE HEPTAHYDRATE	1 g in 1 g	

F	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:21130-602- 06	454 g in 1 POUCH; Type 0: Not a Combination Product	11/12/2002		
2	NDC:21130-602- 01	1814 g in 1 POUCH; Type 0: Not a Combination Product	11/12/2002		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/12/2002	

Labeler - Safeway Inc (009137209)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(21130-602)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(21130-602)	

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