EPSOM SALT- magnesium sulfate granule, for solution
TOPCO Associates, LLC

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.

Drug Facts

To Open

Cut along dotted line and press zipper to reseal

TEP

Tamper Evident Packaging:

Caution: This package has been sealed for your protection. do not use if package is open, torn or multiated

Active ingredient

Active ingredient

Magnesium sulfate USP (Heptahydrate) 100%

purpose

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

For Soaking

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

Warnings

Warnings for Soaking

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.

Ask a Doctor before use

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet
- abdominal pail, 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

Ask a doctor or pharmacist befoe 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

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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 liquie 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

Directions for Soaking

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.

Other information

Other information

- magnesium content 495 mg per teaspoon (5 grams)

Adverse reaction section

DISTRIBUTED BY TOPCO ASSOCIATES, LLC

ELK GROVE VILLAGE, IL60007

1-888-423-0139

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Principal display panel

TOPCARE

Epsom

Salt

MAGNESIUM SULFATE U.S.P.

$MgSO_4 \cdot 7H_2O$

Saline Laxative

- For relief of Occasional Constipation

Soaking Aid

- For Minor Sprains and Bruises

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:36800-602
Route of Administration	ORAL, TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MAGNESIUM SULFATE (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE	1 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-602-43	454 g in 1 POUCH		
2	NDC:36800-602-07	1814 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part334	07/15/1999	

Labeler - TOPCO Associates, LLC (006935977)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(36800-602)

Revised: 1/2013 TOPCO Associates, LLC