

EPSOM SALT- magnesium sulfate granule, for solution
FOODHOLD U.S.A., 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.

Epsom Salt

TEP

Tamper Evident Packaging:

Caution: this package has been sealed for your protection.

Do not use if package is open, torn or mutilated

Claims

Epsom Salt

Magnesium Sulfate U.S.P.

$MgSO_4 \cdot 7H_2O$

Active ingredient

Magnesium sulfate USP (heptahydrate) 100%

Purpose

Saline Laxative

External use soaking aid

Uses

- for relief of occasional constipation (irregularity)
- this product generally produces bowel movement in 1/2 to 6 hours

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

Warnings

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

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

Directions for Soaking:

Dissolve 2 cups of CareOne Epsom Salt per gallon of water. Apply with bandages or toweling for 30 minutes up to three times a day. For less intensive soak, use 1 or 2 cups in a bath. Use warm water for best results

Other information

- magnesium content 495 mg per teaspoon (5 grams)

Adverse Reactions

DISTRIBUTED BY:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

Quality Guaranteed or your money back.

principal display panel

CAREONE

EPSOM

SALKT

MAGNESIUM SULFATE U.S.P.

- SALINE LAXATIVE
- SOAKING AID

For relief of occasional constipation

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:41520-055 |
| 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:41520-055-43 | 454 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:41520-055-07 | 18.14 g in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 05/06/2015 | |

Labeler - FOODHOLD U.S.A., LLC (809183973)

Registrant - Vi-Jon (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Vi-Jon | | 790752542 | manufacture(41520-055) |

Revised: 5/2015

FOODHOLD U.S.A., LLC