

EPSOM SALT- magnesium sulfate granule, for solution

Vi-Jon

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

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

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

Epsom Salt

MAGNESIUM SULFATE U.S.P.

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.

Distributed by Vi-Jon

One Swan Drive

Smyrna, TN 37167

principal display panel

Mountain Falls

Naturally derived

For a soothing, relaxing bath, add to warm bath

Reduce stiffness and soreness

Warm and comfort your muscle aches

Epsom Salt

magnesium sulfate USP

saline laxative for relief of occasional constipation

soaking aid for minor sprains and bruises

NET WT 1 LB (454 g)

www.mymountainfalls.com



principal display panel

Cut along dotted line and press zipper to reseal.

NDC 0869-002-07

swan

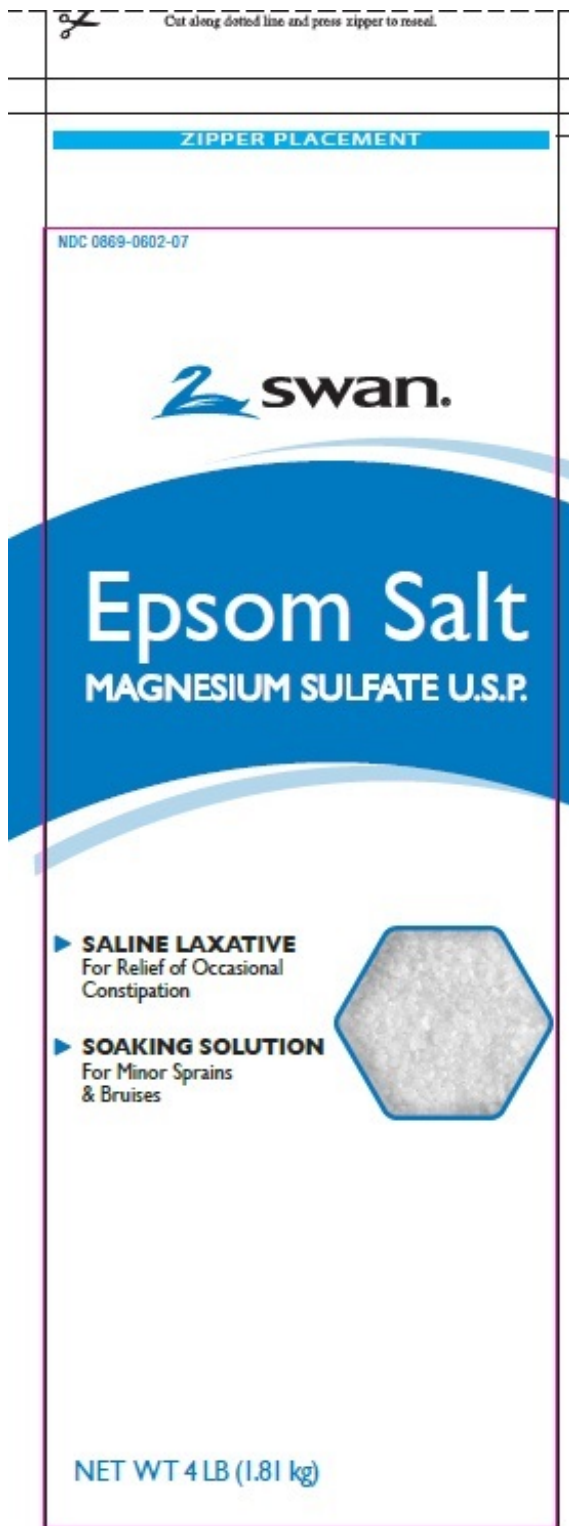
Epsom Salt

MAGNESIUM SULFATE U.S.P.

- SALINE LAXATIVE - For Relief of Occasional Constipation
- SOAKING SOLUTION - For Minor Sprains & Bruises

NET WT 4 LB (1.81 kg)

602.002/602AA



EPSOM SALT

magnesium sulfate granule, for solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0869-0602 |
| 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:0869-0602-43 | 454 g in 1 POUCH; Type 0: Not a Combination Product | 07/15/1998 | |
| 2 | NDC:0869-0602-10 | 1814 g in 1 POUCH; Type 0: Not a Combination Product | 07/15/1998 | |
| 3 | NDC:0869-0602-45 | 907 g in 1 POUCH; Type 0: Not a Combination Product | 07/15/1998 | |
| 4 | NDC:0869-0602-34 | 227 g in 1 POUCH; Type 0: Not a Combination Product | 07/15/1998 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 07/15/1998 | |

Labeler - Vi-Jon (790752542)**Registrant** - Vi-Jon (790752542)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Vi-Jon | | 790752542 | manufacture(0869-0602) |

Revised: 1/2020

Vi-Jon