

**ASSURED EPSOM SALT- magnesium sulfate granule
Greenbrier International, 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.

Assured Epsom Salt

Active Ingredients

Magnesium Sulfate (heptahydrate) 100%

Purpose

Saline laxative

Uses

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

KEEP OUT OF REACH OF CHILDREN

If pregnant or breast feeding, ask a health professional before use. In Case of overdose, get medical help or contact a Poison Control Center right away.

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.

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

Directions

- do not exceed more than 2 doses per day
- drink a full glass (8 ounces) of liquid with each dose
- 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 4 level teaspoons (10 to 20 grams) daily

children 6 to under 12 year - 1 to 2 level teaspoons (5 to 10 grams) daily

children under 6 year - consult a doctor

None Available



Assured
 Multi-Purpose
 Epsom Salt
 Natural Magnesium Sulfate
 All Natural
 Net WT 16 OZ (454g)

| ASSURED EPSOM SALT | | | | |
|--|------------------|---|----------------------|--------------------|
| magnesium sulfate granule | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:33992-3020 | |
| Route of Administration | ORAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM CATION - UNII:T6V3LHY838) | | MAGNESIUM SULFATE HEPTAHYDRATE | 100 g in 100 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| SULFUR (UNII: 70FD1KFU70) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:33992-3020-1 | 454 g in 1 BAG; Type 0: Not a Combination Product | 06/14/2016 | |
| Marketing Information | | | | |

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 06/14/2016 | |

Labeler - Greenbrier International, Inc. (610322518)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|-------------------------|
| Greenbrier International, Inc. | | 529047265 | manufacture(33992-3020) |

Revised: 2/2019

Greenbrier International, Inc.