

**EPSOM SALTS- magnesium sulfate granule
International Wholesale 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.

Health Smart Epsom Salts

Active Ingredients Purpose

Magnesium Sulfate (heptahydrate) 100% Saline Laxative

Uses

- For relief of Occasional Constipation (Irregularity)
- This product generally produces bowel movement

Keep out of reach of children. 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 any other drugs. Laxative 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 of longer than 1 week

If pregnant or breast-feeding ask a health profesional before use

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 years: 1 to 2 level teaspoons (5 to 10 grams) daily
- children under 6 years: consult a doctor

There are no inactive ingredients

Health Smart

Mutli purpose

Epsom Salts

Net Wt. 16 oz (454 g)



EPSOM SALTS

magnesium sulfate granule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-202
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	100 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-202-01	454 g in 1 POUCH; Type 0: Not a Combination Product	07/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/09/2019	

Labeler - International Wholesale Inc. (161872676)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-202)

Revised: 7/2022

International Wholesale Inc.