EPSOM SALT- magnesium sulfate crystal Cardinal Health

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.

Leader Epsom Salt

Caution: this package has been sealed for your protection. Do not use if package is open, torn or mutilated

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 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

Other information

• magnesium content 495 mg per teaspon (5 grams)

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 toweling for 30 minutes up to three times a day, or use as a soak or in a 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 CARDINAL HEALTH, DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6313

Principal Display Panel

Cut along dotted line and press zipper to reseal.

NDC 37205-602-07

LEADER Epsom Salt

Magnesium Sulfate U.S.P.

 $M_{\parallel g} \square SO_{\parallel 4} \square 7H_{\parallel 2} \square 0$

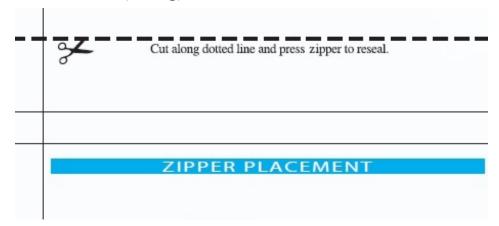
Saline Laxative

For Relief of Occasional Constipation

Soaking Aid

For Minor Sprains and Bruises

NET WT 4 LB (1.81 kg)



NDC 37205-602-07



Epsom Salt

Magnesium Sulfate U.S.P. MgSO4 • 7H2O

Saline Laxative
For Relief of Occasional
Constipation

Soaking AidFor Minor Sprains and Bruises





602.002/602AA

EPSOM SALT

magnesium sulfate crystal

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:37205-602

Route of Administration ORAL, TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength			
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNES CATION - UNII:T6V3LHY838)	GIUM MAGNESIUM SULFATE HEPTAHYDRATE	1 g in 1 g			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-602-07	1814 g in 1 POUCH; Type 0: Not a Combination Product	03/26/2012	
2	NDC:37205-602-43	454 g in 1 POUCH; Type 0: Not a Combination Product	03/26/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/26/2012	

Labeler - Cardinal Health (097537435)

Registrant - Vi-Jon (790752542)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vi-Jon		790752542	manufacture(37205-602)		

Revised: 8/2017 Cardinal Health