EPSOM SALT- magnesium sulfate granule TOP CARE (Topco Associates 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.

Drug Facts

Active ingredient

Magnesium sulfate USP 100%

Purpose

Saline laxative

Uses

- relieves occasional constipation (irregularity)
- 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
- stomach pain, nausea or vomiting
- noticed a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug.

When using this product

do not use more than directed

Stop use and ask a doctor if

- you have rectal bleeding or failure to have a bowel movement after use. This may indicate a serious condition.
- you need to use a laxative for more than 1 week

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 (1-800-222-1222) right away.

Directions

• do not exceed more than 2 doses per day; if necessary repeat dosage in 4 hours

age	dose
adults and children 12 years and	2-4 level teaspoons dissolved in a full glass (8oz) of
older	water
children 6 to 11 years	1-2 level teaspoons in a full glass (8oz) of water

Not recommended for children under 6 years of age.

Other information

• each teaspoon contains: magnesium 495 mg

Inactive ingredient

none

Principal Display Panel

Epsom Salt

MAGNESIUM SULFATE U.S.P.

- Saline Laxative for Relief of Occasional Constipation
- Soaking Aid for Minor Sprain and Bruises

NET WT OZ (LB)

TAMPER EVIDENT: DO NOT USE IF HEAT SEALED POUCH IS IMPROPERLY SEALED.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

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www.topcarebrand.com

Package Label

TAMPER EVIDENT: DO NOT USE IF HEAT SEALED POUCH IS IMPROPERLY SEALED.



36800-395

Epsom Salt

MAGNESIUM SULFATE U.S.P.

- Saline Laxative for Relief of Occasional Constipation
- Soaking Aid for Minor Sprains and Bruises



NET WT 16 OZ (1 LB) 454 g



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TOPCARE HEALTH Epsom Salt

EPSOM SALT

magnesium sulfate granule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-395
Poute of Administration	ORAL TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNS PECIFIED	1 g in 1 g	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-395- 01	454 g in 1 CARTON; Type 0: Not a Combination Product	04/30/2014	
2	NDC:36800-395- 04	1810 g in 1 CARTON; Type 0: Not a Combination Product	04/30/2014	
3	NDC:36800-395- 10	454 g in 1 POUCH; Type 0: Not a Combination Product	04/30/2014	
4	NDC:36800-395- 40	1814 g in 1 POUCH; Type 0: Not a Combination Product	04/30/2014	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

OTC monograph not final	part334	04/30/2014	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022 TOP CARE (Topco Associates LLC)