# EPSOM SALT- magnesium sulfate granule, for solution 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.

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#### Drug Facts Top Care 602 902.002/602AA

#### To Open

Cut along dotted line and press zipper to reseal

#### TEP

#### **Tamper Evident Packaging:**

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

#### 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

#### **For Soaking**

For external use as a soaking aid for minor sprains and bruises.

#### Warnings

#### Warnings for Soaking

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.

#### 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

#### **Directions for Soaking**

**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.

#### Other information

• magnesium content 495 mg per teaspoon (5 grams)

#### Adverse reaction section

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#### principal display panel

Cut along dotted line and press zipper to reseal. TopCare Epsom Salt MAGNESIUM SULFATE U.S.P. MgSO4 - 7H2O

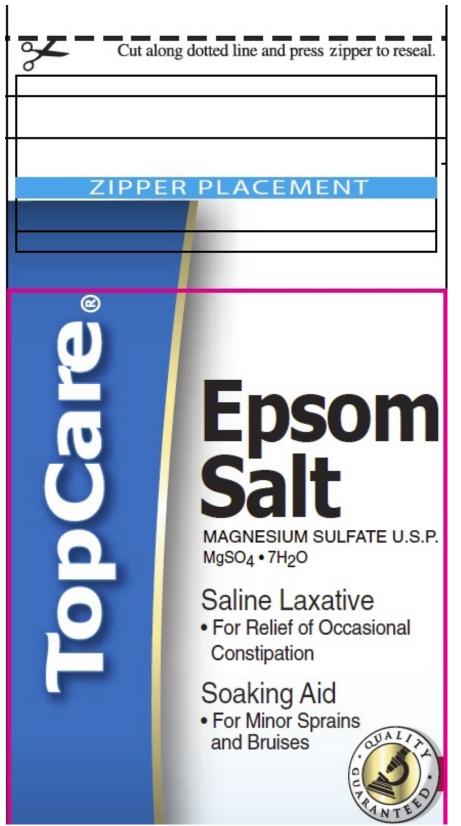
Saline Laxative

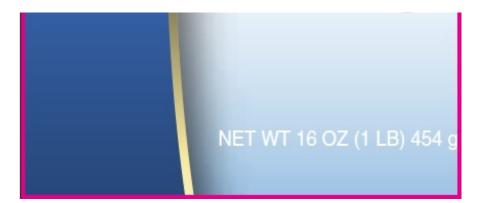
• For Relief of Occasional Constipation

Soaking Aid

• For Minor Sprains and Bruises

NEW WT 16 OZ (1 LB) 454g





### **EPSOM SALT**

Product Informat	ion						
Product Type		HUMAN OTC DRUG	Ite m Co	Item Code (Source)		NDC:36800-602	
Route of Administration		ORAL, TOPICAL					
Active Ingredient	/Active Moi	ety					
Ingredient Name					Basis of Strength		Strength
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM CATION - UNII:T6V3LHY838)				MAGNESIUM SULFA HEPTAHYDRATE		FATE	
			MAGINESIUM				1g in 1g
			WAGNESION				1g in 1g
CATION - UNII:T6V3LF			MAGNESIUM				1 g in 1 g
CATION - UNII:T6V3LF Packaging		Package Description					
CATION - UNII:T6V3LF Packaging # Item Code	FY838)				HEPTAHYDRATE eting Start Date		
CATION - UNII:T6V3LF Packaging J Item Code NDC:36800-602-01	IY838) 454 g in 1 POU	Package Description	on Product	Mark	HEPTAHYDRATE eting Start Date 999		
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CATION - UNII:T6V3LF Packaging I Item Code NDC:36800-602-01	IY838) 454 g in 1 POU	<b>Package Description</b> CH; Type 0: Not a Combination	on Product	<b>Mark</b> 07/15/1	HEPTAHYDRATE eting Start Date 999		
CATION - UNII:T6V3LF Packaging I tem Code NDC:36800-602-01 NDC:36800-602-07	IY8 38) 454 g in 1 POU 18 14 g in 1 POU	<b>Package Description</b> CH; Type 0: Not a Combination	on Product	<b>Mark</b> 07/15/1	HEPTAHYDRATE eting Start Date 999		
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Labeler - TOPCO Associates, LLC (006935977)

## Registrant - Vi-Jon (790752542)

Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
Vi-Jo n		790752542	manufacture(36800-602)					