# EPSOM SALT- epsom salt granule QUALITY CHOICE (Chain Drug Marketing Association)

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**

### **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 pregnancy 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 dissolved 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

#### Questions or comments?

For laxative or soak, call 1-248-449-9300 Monday- Friday 9AM-5PM EST

# **Principal Display Panel**

## **Epsom Salt**

Saline Laxative

Magnesium Sulfate U.S.P.

Relieves Occasional Constipation

Soaking Aid For Minor Sprains and Bruises

Relief Throughout the Year

### \*Safety Sealed

Net WT LB (kg)

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

Distributed by: C.D.M.A., Inc.©

43157 W. Nine Mile

## Package Label



## **QUALITY CHOICE Epsom Salt**

#### **EPSOM SALT** epsom salt granule **Product Information** HUMAN OTC DRUG **Item Code (Source)** NDC:63868-937 **Product Type Route of Administration** ORAL. TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB) (MAGNESIUM MAGNESIUM SULFATE, 1 g in 1 g **UNS PECIFIED** CATION - UNII:T6V3LHY838)

ackaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:63868-937-	454 g in 1 POUCH; Type 0: Not a Combination Product	12/31/2017	12/31/2025		
NDC:63868-937-	1814 g in 1 POUCH; Type 0: Not a Combination Product	12/31/2017	12/31/2025		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	12/31/2017	12/31/2025	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023 QUALITY CHOICE (Chain Drug Marketing Association)