

HARMON CORE VALUES EPSOM SALT- magnesium sulfate granule, for solution

HARMON STORES, 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.

Harmon Core Values Epsom Salt

Active ingredient (in each teaspoon)

Magnesium Sulfate (Epsom Salt) 5 g

Purpose

External Use Soaking Solution
Internal Use Saline Laxative

Uses

External

- temporarily relieves minor sprains and bruises

Internal

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 1/2 to 6 hours

Warnings

As a laxative • Do not give to children under six years of age except under the advice and supervision of a physician.

- **For occasional use only. Serious side effects from prolonged use or overdose may occur.**

Ask a doctor before use if you have:

As a soaking solution

- redness or swelling present
- evidence of an infection
- diabetes - hot and warm soaks should not be used by individuals with diabetes except on advice of a physician

As a laxative

- abdominal pain

- nausea
- vomiting
- kidney disease
- a sudden change in bowel habits that lasts over 2 weeks
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are:

As a laxative • taking prescription medication

When using this product

- do not use more than directed

Stop use and ask a doctor if:

As a soaking solution

- you experience redness, irritation, swelling or infection.

As a laxative

- you have no bowel movement within six hours or experience rectal bleeding - these could be signs of a serious condition.
- you have already used a laxative for longer than one week.

If pregnant or breastfeeding

consult a health care professional before use.

Keep out of reach of children.

In case of accidental ingestion or overdose, seek medical attention or contact a Poison Control Center immediately.

Directions

As a soaking solution: Pour 2 cups of Epsom Salt under warm, running bath water. Soak for 20 minutes to relieve sore, tired muscles.

As a warm compress: Dissolve 1 cup of Epsom Salt in 1 quart of warm water. Using a towel, apply solution to the affected area for 15-30 minutes to reduce pain and swelling. Repeat as needed.

As a laxative: If necessary, repeat dosage after 4 hours. Do not take more than 2 doses per day. Drink a full 8 oz of water with each dose.

adults and children 12 years of age and older1-3 level teaspoons dissolved in a full glass (8oz) of water daily.

children 6 to 12years of age1/2-1 level teaspoons dissolved in a full glass (8oz) of water daily.

Not recommended for children under 6 years of age

Other information

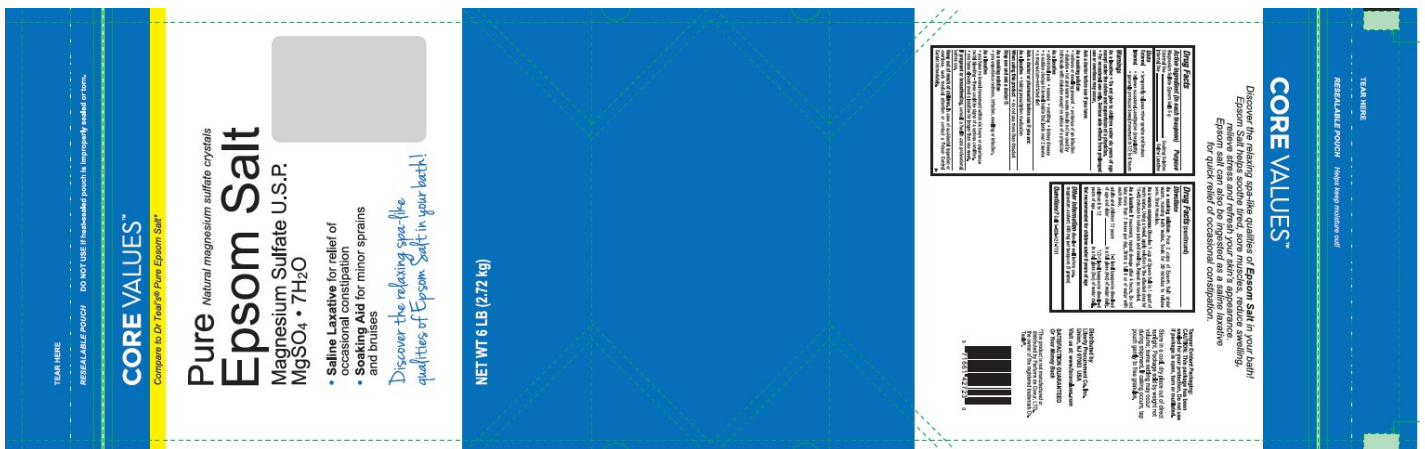
dissolve well before use.

magnesium content: 495 mg per teaspoon (5 grams)

Inactive ingredient

None

Label



HARMON CORE VALUES EPSOM SALT

magnesium sulfate granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-080
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	1 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-080-90	2720 g in 1 POUCH; Type 0: Not a Combination Product	01/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/15/2019	

Labeler - HARMON STORES, INC. (804085293)

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HARMON STORES, INC.