

SPEARMINT AND MENTHOL SCENTED NATURAL EPSOM SALT- magnesium sulfate powder

Anhui Twowin Machinery Imp. & Exp. Co., Ltd.

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.

Active Ingredient Purpose

Magnesium Sulfate USP (Epsom Salt)

Internal Use Saline Laxative

External Use Soaking Solution

Uses (Internal)

- Relieves occasional constipation (irregularity)
- Generally produces bowel movements in 1/2 to 6 hours

Uses (External)

- Relieves pain from minor sprains and bruises

Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Directions - For Internal Use as a Laxative

- do not exceed more than 2 doses per day
- may be taken as a single daily dose or in divided doses
- dissolve each dose in a full (8 ounces) of liquid

Age	Dose
adults and children 12 years and older	2 to 4 level teaspoons (10 to 20 grams) daily
children 6 to under 12 years	1 to 2 level teaspoons (5 to 10 grams) daily

Not recommended for children under 6 years of age.

Natural Epsom Salt

Magnesium Sulfate U.S.P.

Soaking Solution

Saline Laxative

Soothes Minor Aches, Sprains & Sore Muscles

Calming & Rejuvenating

SORE FEET RELIEF: Add one cup of Amoray Care® Epsom Salt to one gallon of warm water and soak for at least 5 minutes at a time.

BATH SOAK: Add two cups of Amoray Care® Epsom Salt under warm running bath water to release its gentle aroma. Amoray Care® Epsom Salt helps relieve tension and provides a soothing, relaxing experience. Soak for at least 20 minutes.

First Aid Compress: Dissolve 2 cups of Amoray Care® Epsom Salt into two cups of hot water to make

a compress, apply as a wet dressing with a towel to: soothe bruises & sprains, take the sting out of insect bites, draw out splinters, alleviate pain from sports and overexertion.

Keep out of reach of children. Where prompt relief is not obtained or where there is evidence of infection, discontinue use and consult a physician. Hot or warm soaks should not be used by individuals with diabetes except on advice of a physician. Avoid contact with eyes.

EPSOM SALT WITHOUT SCENT CAN BE APPLIED FOR BOTH INTERNAL AND EXTERNAL USE, SCENTED EPSOM SALTS CAN BE APPLIED FOR EXTERNAL USE ONLY.

Store in a cool, dry place out of direct sunlight. Package sold by weight not volume, some settling may occur during shipment. If caking occurs, tap pouch gently to free granules.

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 presently taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work.

When using this product, do not use more than directed.

Stop and consult a doctor if:

As laxative: • you have rectal bleeding or fail to have a bowel movement after use. This may indicate a serious condition. • You need to use a laxative for more than 1 week

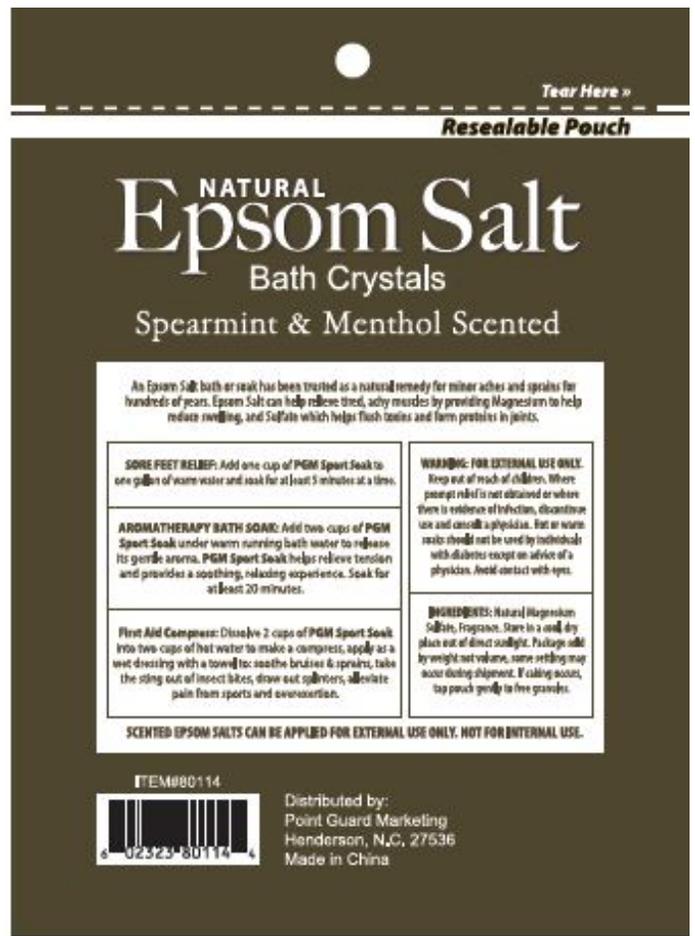
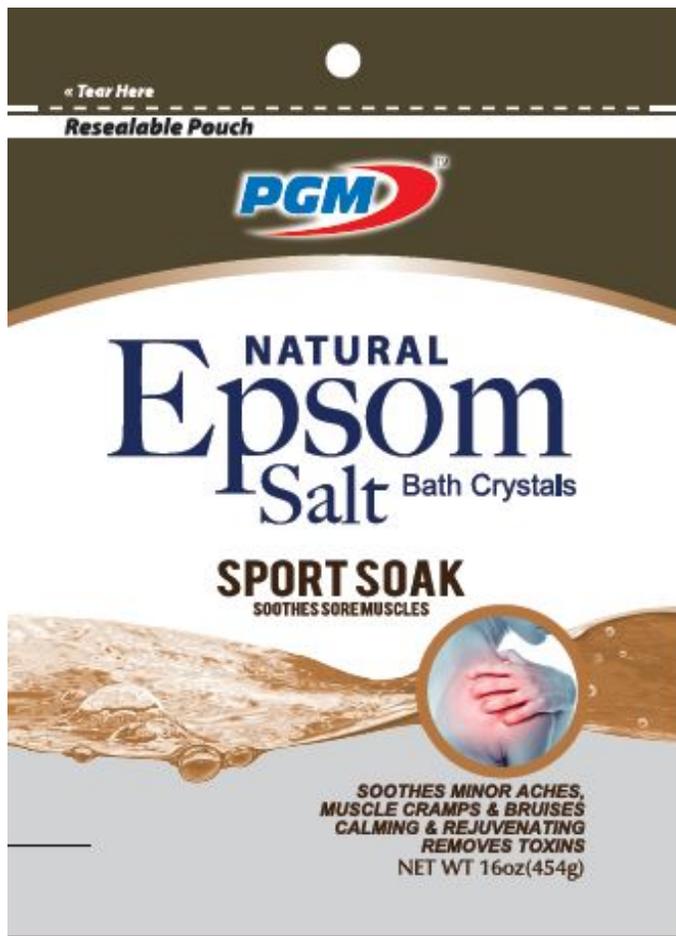
As soaking solution: • you have redness, irritation, swelling, or infection occurs • hot or warm soaks should not be used by individuals with diabetes except with the advice of a physician

If pregnant or breast-feeding, ask a health professional before use.

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Ingredients:

Natural Magnesium Sulfate



SPEARMINT AND MENTHOL SCENTED NATURAL EPSOM SALT

magnesium sulfate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69232-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE	10 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
SPEARMINT (UNII: J7I2T6IV1N)	
MENTHOL (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69232-005-01	454 g in 1 PACKAGE; Type 0: Not a Combination Product	01/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/27/2016	

Labeler - Anhui Twowin Machinery Imp. & Exp. Co., Ltd. (421251758)

Establishment

Name	Address	ID/FEI	Business Operations
Anhui Twowin Machinery Imp. & Exp. Co., Ltd.		421251758	manufacture(69232-005)

Revised: 2/2016

Anhui Twowin Machinery Imp. & Exp. Co., Ltd.