

HEALTH SMART NATURAL EPSOM SALT- magnesium sulfate granule, for solution
International Wholesale, 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.

Drug Facts

Active Ingredient

Magnesium Sulfate USP (Epsom Salt)

Purpose

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 major sprains and bruises

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.

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

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

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

SORE FEET RELIEF: Add one cup of HealthSmart™ Epsom Salt to one gallon of warm water and soak at least 5 minutes at a time.

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

First Aid Compress: Dissolve 2 cups of HealthSmart™ 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.

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INGREDIENTS: Natural Magnesium Sulfate

Store in 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.

**MADE IN CHINA . DISTRIBUTED BY:
homesmart™
PRODUCTS
SOUTHFIELD, MI 48075
WWW.HOMESMARTPRODUCTS.COM
NDC#52862-200**

Package Label

HEALTH
SMART™

NATURAL

Epsom
Salt

Magnesium Sulfate U.S.P
Soaking Solution
Saline Laxative

*Soothes Minor Aches, Sprains & Sore Muscles
Calming & Rejuvenating*

NET WT 16 OZ (454g)

<p>Drug Facts</p> <p>Active Ingredient..... Purpose Magnesium Sulfate USP (Epsom Salt)..... Saline Laxative</p> <p>Internal Use..... External Use Soaking Solution</p> <p>Uses (Internal) - Relieves occasional constipation (irregularity) - Generally produces bowel movements in 1/2 to 6 hours</p> <p>Uses (External) - Relieves pain from minor sprains and bruises</p> <p>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</p> <p>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.</p> <p>When using this product, do not use more than directed.</p> <p>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</p> <p>If pregnant or breast-feeding, ask a health professional before use. 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. EPSOM SALT WITHOUT SCENT CAN BE APPLIED FOR BOTH INTERNAL AND EXTERNAL USE. SCENTED EPSOM SALTS CAN BE APPLIED FOR EXTERNAL USE ONLY.</p> <p>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</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>adults and children 12 years and older</td> <td>2 to 4 level teaspoons (10 to 20 grams) daily</td> </tr> <tr> <td>children 6 to under 12 years</td> <td>1 to 2 level teaspoons (5 to 10 grams) daily</td> </tr> </tbody> </table> <p>Not recommended for children under 6 years of age.</p>	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	 <p>NATURAL Epsom Salt</p> <p>Magnesium Sulfate U.S.P. Soaking Solution Saline Laxative</p> <p><i>Soothes Minor Aches, Sprains & Sore Muscles Calming & Rejuvenating</i></p> <p>NET WT 16 OZ (454g)</p>	<p>SORE FEET RELIEF: Add one cup of HealthSmart™ Epsom Salt to one gallon of warm water and soak for at least 5 minutes at a time.</p> <p>BATH SOAK: Add two cups of HealthSmart™ Epsom Salt under warm running bath water to release its gentle aroma. HealthSmart™ Epsom Salt helps relieve tension and provides a soothing, relaxing experience. Soak for at least 20 minutes.</p> <p>First Aid Compress: Dissolve 2 cups of HealthSmart™ 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.</p> <p>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.</p> <p>EPSOM SALT WITHOUT SCENT CAN BE APPLIED FOR BOTH INTERNAL AND EXTERNAL USE. SCENTED EPSOM SALTS CAN BE APPLIED FOR EXTERNAL USE ONLY.</p> <p>INGREDIENTS: Natural Magnesium Sulfate</p> <p>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.</p> <p>MADE IN CHINA - DISTRIBUTED BY:  SOUTHFIELD, MI 48075 WWW.HOMESMARTPRODUCTS.COM</p> <p>HS-01055</p>  <p style="writing-mode: vertical-rl; transform: rotate(180deg);">NDC# 52862-200</p>
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HEALTH SMART NATURAL EPSOM SALT

magnesium sulfate granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-200
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE	1 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:52862-200-16	454 g in 1 CARTON		
2	NDC:52862-200-22	624 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/01/2013	

Labeler - International Wholesale, Inc. (161872676)

Revised: 10/2013

International Wholesale, Inc.