

EPSOM SALT SOAKING SOLUTION- magnesium sulfate granule
Advanced Beauty Systems, 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.

Dr. Teals Magnesium sulfate U.S.P.

Active ingredient	Purpose
Magnesium Sulfate USP (Epsom Salts)	
External use	Soaking solution
Internal Use	Saline Laxative

Uses

External: Relieves pain from minor sprains and bruises

Internal: Relieves occasional constipation (irregularity)

generally produces bowel movement in 1/2 to 6 hours.

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

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

Stop use and consult a doctor if:

As a soaking solution

- you experience redness, irritation, swelling , or infection

As a laxative

- you have no bowel movements within six hours or experience rectal bleeding-these could be signs of a serious condition

- you need a laxative for more than a week

Warnings:

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.

Do not take this product except under the advice and supervision of a physician if you:

- Have kidney disease

- Are taking prescription medication

- Have a magnesium restricted diet

Ask a doctor before 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

Dr. Teal's[®]

Therapeutic Solutions

Magnesium Sulfate U.S.P.

Dr. Teal's[®] combines Magnesium and Sulfate - the natural minerals that make up pure Epsom Salt - for whole body relief and wellness. Use Dr. Teal's[®] to revitalize tired, achy muscles, reduce stress, minimize swelling and refresh skin's appearance. Epsom Salt can also be ingested as a Saline Laxative for quick relief.

Also try Dr. Teal's[®] fragrant Epsom Salt Soaking Solution, infused with essential oils like Lavender & Eucalyptus Spearmint for a spa-like experience, and Dr. Teal's[®] award-winning Epsom Salt Foot Soak with Peppermint essential oil.

Drug Facts

Active ingredient

Magnesium Sulfate USP (Epsom Salt)

External use.....Soaking Solution

Internal use.....Saline Laxative

Purpose

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

Warnings

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.

Do not take this product except under the advice and supervision of a physician if you: ■ have kidney disease ■ are taking prescription medication ■ have a magnesium restricted diet

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

- Stomach Pain ■ Nausea ■ Kidney Disease
 ■ A sudden change in bowel habits that lasts over 2 weeks

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

Stop use and consult 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 need a laxative for more than one week

If pregnant or breastfeeding, consult a physician before use.

Directions ■ do not exceed more than 2 doses per day; if necessary repeat dosage in 4 hours

For external use

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.

For internal use

As a laxative

adults and children.....2-4 level teaspoons dissolved
 12 years and olderin a full glass (8oz) of water.
 children 6 to 12.....1-2 level teaspoons dissolved
 years of agein a full glass (8oz) of water.

Not recommended for children under 6 years of age

Other information

dissolve well before use

This finished product is not tested on animals.

Made in the U.S.A.

Distributed By:
 Advanced Beauty Systems, Inc.
 Dallas, TX 75240

Dr. Teal's[®] is a registered trademark of Advanced Beauty Systems, Inc.

For more information about
 the benefits of Epsom Salt visit
www.drteals.com



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



Dr. Teal's

Therapeutic solutions

Epsom Salt Soaking Solution

Magnesium Sulfate USP

Sooths aches, pains, sprains and stings

Helps relieve muscle tension

Made in U.S.A. with pure Epsom Salt

Net Wt. 2.72 Kg 6 lbs



HELPS KEEP MOISTURE OUT!

Dr. Teal's[®]

Therapeutic Solutions

Epsom Salt Soaking Solution

Magnesium Sulfate U.S.P.



- + Soothes aches, pains, sprains & stings
- + Helps relieve muscle tension
- + Made in the U.S.A. with pure Epsom Salt

NET WT 2.72 Kg 6 LBS

.375" Seal

.375" Seal

EPSOM SALT SOAKING SOLUTION

magnesium sulfate granule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51345-099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE	2.72 kg in 2.72 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51345-099-01	2.72 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/13/2012	

Labeler - Advanced Beauty Systems, Inc. (129986613)

Registrant - Giles Chemical, a division of Premier Magnesia, LLC (003162435)

Establishment

Name	Address	ID/FEI	Business Operations
Giles Chemical, a division of Premier Magnesia, LLC		003162435	manufacture