PEPSOM FLYING P EPSOM SALT - magnesium sulfate for solution The Pepsom Group, 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.

Flying P Epsom Salt Drug Facts

Active Ingredient

Magnesium Sulfate U.S.P. 100% (Epsom salt)

PURPOSE

Externa	lSoaking Solution
Internal.	Saline Laxative

Uses

External-

Soaking Solution......Relieves muscle strains and soreness

Internal-

Saline Laxative.....Relieves occasional constipation

Warnings

Laxative

- For occasional use only. Serious side effects from prolonged use or overdosage may occur. Do not take this product except under the advice and supervision of physician if you
 - have kidney disease
 - are taking medications

Do not give to children under 6 years of age except under the advice and supervision of a physician.

Ask a doctor before use if you have

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 physician

Laxative

- kidney disease
- stomach pain
- nausea
- a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor:

Laxative

- if you have no bowel movement within 6 hours or rectal bleeding. These could be signs of a serious condition
 - you need a laxative for more than one week

When using this product

• avoid contact with eyes or mucus membranes

If pregnant 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 right away

Directions

Soaking Solution:

Bath - Dissolve 2 cups into a tub of hot water and soak for 15-30 minutes **Foot or Wrist Soak** - Dissolve 2 cups into a foot bath half-full of water, soaking the injured area for 20-30 minutes. Repeat 2-3 times per day until relief is obtained

Laxative:

INACTIVE INGREDIENTS

None

Questions? Comments?

1-877-FEEL-PEP

Principal Display Panel



RESEALABLE POUCH CUT ALONG DOTTED LINE

Epsom Salt

MAGNESIUM SULFATE U.S.P.

Soaking Aid

• for minor sprains and bruises

Saline Laxative

• for relief of occasional constipation

NET WT 4 LB (1.81 kg)

RESEALABLE POUCH CUT ALONG DOTTED LINE

EPSOM SALT IS 100% NATURAL MINERAL (Magnesium Sulfate U.S.P.). ENJOY THE MANY DELIGHTFUL USES AND BENEFITS OF THIS PURE EPSOM SALT PRODUCT.

EPSOM SALT

FOR EVERY SEASON

WINTER BLUES? ADD 2 CUPS TO A WARM/HOT BATH SOAK 15-30 MIN FOR RELIEF OF ACHES AND PAINS

SPRING BREAK? ADD A CUP INTO WASHCLOTH AND SCRUB OVER BODY TO EXFOLIATE SKIN - RINSE

SUMMER BUMMER? FOR CONCENTRATED RELIEF FROM STINGS OR PAIN, ADD 1/2 CUP

TO 1 QT. OF WATER - MAKE A DRESSING AND WRAP INJURED AREA 2-3 X A DAY

FALL SHORT? FOR FOOT PAIN, ADD 1-2 CUPS INTO FOOTBATH OF VERY WARM WATER - SOAK 20-30 MIN

For external use as a soaking aid for minor sprains and bruises.

DIRECTIONS:

Dissolve 2 cupfuls of this product per gallon of water. Apply with bandages or toweling for 30 minutes up to 3 times a day, or use as a soak or in bath. Use warm water for best results.

CAUTION:

If prompt relief is not obtained or if there is evidence of infection, discontinue use and consult your physician. Hot or warm soaks should not be used by individual with diabetes except on the advice of a physician.

KEEP OUT OF REACH OF CHILDREN

100% Satisfaction-Guaranteed or your money back.

Distributed by:

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For information and more great tips Visit us at: www.pepsom.com

PEPSOM FLYING P EPSOM SALT

magnesium sulfate for solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51619-600	
Route of Administration	TOPICAL			

ı	Active Ingredient/Active Moiety					
ı	Ingredient Name	Basis of Strength	Strength			
	Magnesium Sulfate, Unspecified (UNII: DE08037SAB) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Sulfate, Unspecified	1 kg in 1 kg			

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51619-600-84	1.81 kg in 1 BAG		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part334	11/09/2009			

Labeler - The Pepsom Group, Inc. (012727382)

Establishment			
Name	Address	ID/FEI	Business Operations
PACA Foods, Inc.		79 18 0 4 12 3	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
K+S KALI GmbH, Werk Werra, Standort Wintershall		506759815	API MANUFACTURE

Establishment				
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