

**EPSOM SALT- magnesium sulfate crystal granule**  
**Kinray, 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.*

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**Drug Facts**

**Active ingredient**

Magnesium Sulfate USP (epsom salt)

**Purpose**

saline laxative

soaking solution

**Uses**

Internal

relieves occasional constipation (irregularity)

generally produces bowel movement in 1/2 to 6 hours

External

relieves pain from minor sprains and bruises

**Warnings**

ask a doctor before use if you have

kidney disease

a magnesium restricted diet

stomach pain, nausea or vomiting

noticed a sudden change in bowel habits that lasts more than one week

**Ask a doctor or pharmacist before use if you are**

presently taking a prescription drug

**when using this product**

do not use more than directed.

**Stop use and ask a doctor if**

As a laxative,

you have rectal bleeding or no bowel movement after use .

These could be a sign of a serious condition.

you need to use a laxative more than one week.

As a 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 case of accidental overdose, seek professional assistance or contact a poison control center immediately.

**Directions**

For Internal Use as a laxative

Adults and Children 12 years of age and older                      2-4 level teaspoons dissolved in a full glass (8oz) of water.

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

not recommended for children under 6 years of age.

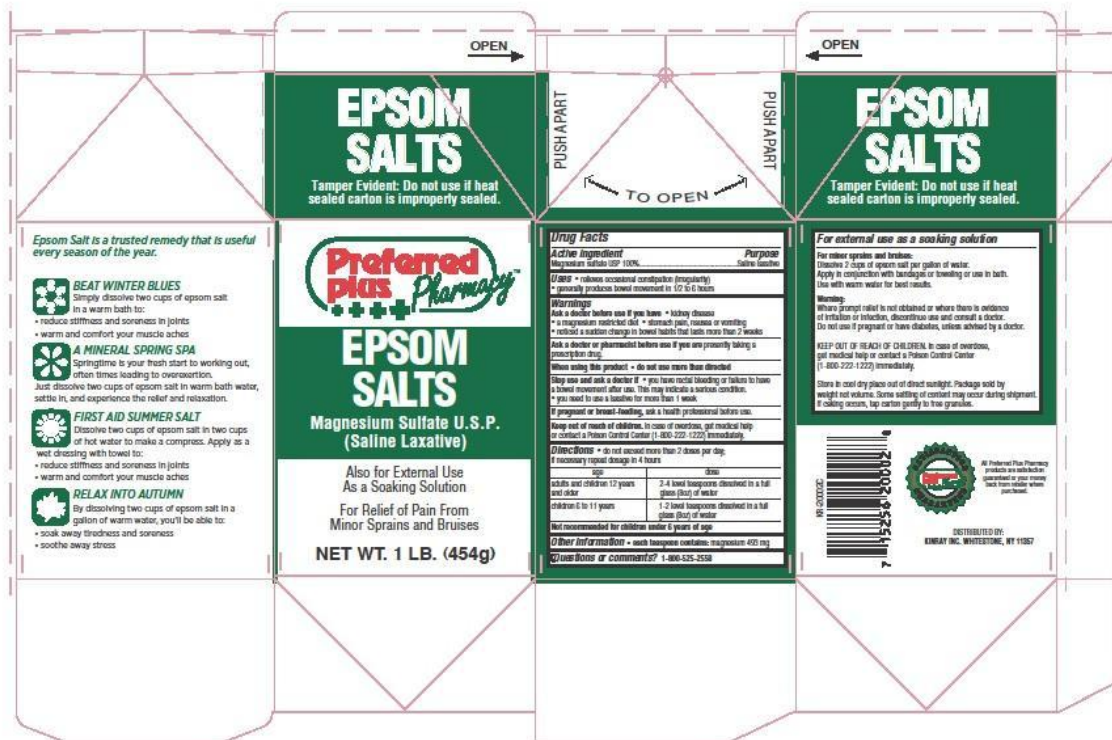
For External Use as a soaking solution

Adults dissolve 1/2 cup in a quart of water, and apply wet, with towel, etc.

As a bathing solution,

2 cups added to the bath water for a refreshing bath after strenuous exertion.

**principal display panel**



PO#

<b>A</b> Aaron Pharmaceuticals		<b>PRODUCT ARTWORK INFORMATION</b>	
Job Title: KR epsom salt 1lb		Colors: PMS 348 ■ PMS 186 ■ BLACK ■	
Aaron Part No:	Date: 5/21/12		
Aaron New No:	Size: N/A		
Aaron rev: C	CR#: 00000		

CR got approved, but no PO to send to print. 6/6/12

None

<b>EPSOM SALT</b>			
magnesium sulfate crystal granule			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63777-204
<b>Route of Administration</b>	ORAL, TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	MAGNESIUM SULFATE (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE	1.81 kg in 100 kg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>

SULFIDE ION (UNII: G15I9 1XETI)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63777-204-01	.454 kg in 1 CARTON		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/14/2012	

**Labeler** - Kinray, Inc. (012574513)

**Registrant** - Aaron Industries, Inc. (030119387)

### Establishment

Name	Address	ID/FEI	Business Operations
Aaron Industries, Inc.		030119387	api manufacture(63777-204) , analysis(63777-204) , label(63777-204)

Revised: 6/2012

Kinray, Inc.