

EPSOM SALT BABY BEAUTY- magnesium sulfate, unspecified granule
Click Products LLC

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.

Magnesium Sulfate USP (Epsom Salt)

Internal UseSaline laxative

External UseSoaking Solution

For internal Use as 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 = Adults and children 12 years and olderDose: 2 to 4 level teaspoons (10 to 22 grams) daily
- Children 6 and under 12 years.....Dose: 1 to 2 level teaspoons (5 to 10 grams) daily
- Not recommended for children under 6 years of age.

USES

Internal

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

External - Relieves pain from minor prains and bruises

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.

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 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 a soaking solution if:

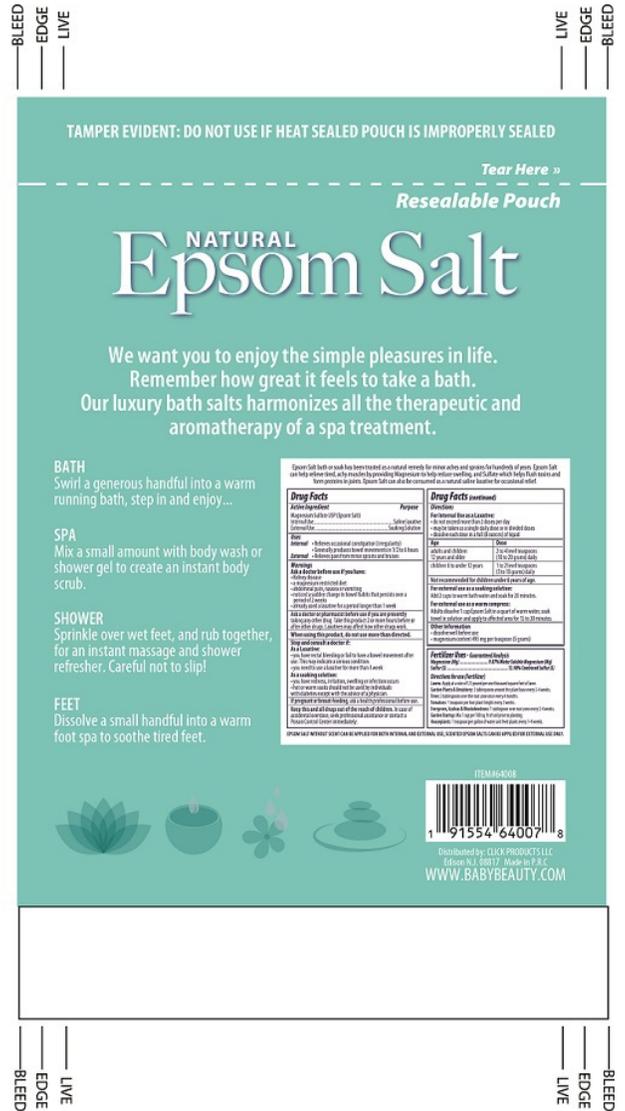
- you have redness, irritation, swelling or infection occurs
- hot or warm soaks should not be used by individuals with diabetes except with the advice of a physician.

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.

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

n/a



EPSOM SALT BABY BEAUTY

magnesium sulfate, unspecified granule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:716 11-0 10
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)		MAGNESIUM SULFATE, UNSPECIFIED	100 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71611-010-02	907 g in 1 BOX; Type 0: Not a Combination Product	10/19/2017	
2	NDC:71611-010-03	1361 g in 1 BAG; Type 0: Not a Combination Product	10/19/2017	
3	NDC:71611-010-01	454 g in 1 BAG; Type 0: Not a Combination Product	10/19/2017	
4	NDC:71611-010-04	1814 g in 1 BAG; Type 0: Not a Combination Product	10/19/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	10/19/2017		

Labeler - Click Products LLC (080766174)

Establishment

Name	Address	ID/FEI	Business Operations
PRIYAL COSMETICS		675482356	manufacture(71611-010)

Revised: 3/2020

Click Products LLC