GREEN TEA CHAMOMILE NATURAL EPSOM SALT- magnesium sulfate powder Anhui Twowin Machinery Imp. & Exp. Co., Ltd.

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.

Active Ingredient	Purpose
Magnesium Sulfate USP (Epsom Salt)	
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 minor sprains and bruises

Example 1 Keep this and all drugs out of the reach of children. Example 1 In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

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
0	2 to 4 level teaspoons (10
years and older	to 20 grams) daily
children 6 to under 12	1 to 2 level teaspoons (5 to
years	10 grams) daily

INot recommended for children under 6 years of age.

Natural Epsom Salt

Magnesium Sulfate U.S.P.

Soaking Solution

Saline Laxative

Soothes Minor Aches, Sprains & Sore Muscles

Calming & Rejuvenating

SORE FEET RELIEF: Add one cup of Amoray Care® Epsom Salt to one gallon of warm water and soak for at least 5 minutes at a time.

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

First Aid Compress: Dissolve 2 cups of Amoray Care® 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.

Kkeep 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.

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

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.

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 Itaking 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: I• 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.

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Ingredients:

Natural Magnesium Sulfate



GREEN TEA CHAMOMILE NATURAL EPSOM SALT

magnesium sulfate powder

Product Informa	tion					
Product Type		HUMAN OTC DRUG	Item Code (Sourc	e)	NDC:69232-	004
Route of Administra	tion	TOPICAL				
Active Ingredien	t/Active Moi	ety				
	In	gredient Name		Basis of	Strength	Strength
MAGNESIUM SULFAT	FE (UNII: DE080	37SAB) (MAGNESIUM CATION -	UNII:T6V3LHY838)	MAGNESIU	M SULFATE	$10\ g$ in $10\ g$
Inactive Ingredie	nts					
		Ingredient Name			Stren	gth
CHAMO MILE (UNII: F	GL3685T2X)					
GREEN TEA LEAF (UI	NII: W2ZU1RY8B	0)				
Packaging						
# Item Code		Package Description	Marketin	ig Start Date	Marketing	g End Date
1 NDC:69232-004-01	454 g in 1 PACK	AGE; Type 0: Not a Combination	Product 01/26/2016			
Marketing Inf	ormation					

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 1/26/20 16	

Labeler - Anhui Twowin Machinery Imp. & Exp. Co., Ltd. (421251758)

Establishment

Name	Address	ID/FEI	Business Operations
Anhui Twowin Machinery Imp. & Exp. Co., Ltd.		421251758	manufacture(69232-004)

Revised: 2/2016

Anhui Twowin Machinery Imp. & Exp. Co., Ltd.