

**MI-ACID REGULAR STRENGTH - aluminum hydroxide, magnesium hydroxide,
dimethicone suspension
TYA Pharmaceuticals**

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 ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200 mg (equivalent to dried gel, USP)

Magnesium hydroxide 200 mg

Simethicone 20mg

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

taking a prescription drug. **Ask a doctor or pharmacist before use if you are**

Antacids may interact with certain prescription drugs.

symptoms last more than 2 weeks **Stop use and ask a doctor if**

ask a health professional before use. **If pregnant or breast-feeding,**

Keep out of reach of children.

Directions

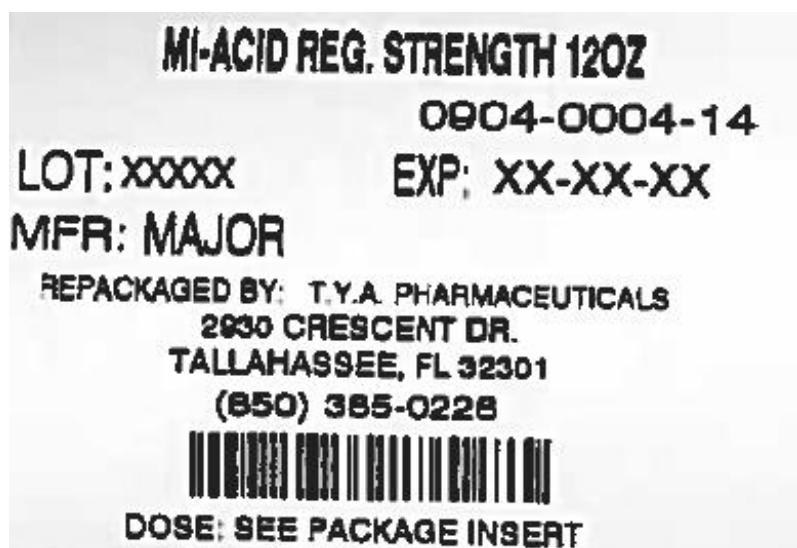
- shake well before use
- adults and children 12 years and older: take 2 to 4 teaspoonfuls between meals, at bedtime, or as directed by a doctor
- do not take more than 24 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks
- children under 12 years: ask a doctor

Other information

- magnesium 85 mg, sodium 1 mg each 5 mL teaspoonful contains:
- store at room temperature
- protect from freezing
- keep tightly closed
- **TAMPER-EVIDENT: Do not use if breakaway band on bottle is missing or broken.**

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor (contains alcohol), hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution



MI-ACID REGULAR STRENGTH

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64725-0004(NDC:0904-0004)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON (lemon)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64725-0004-1	12 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	02/01/2011	

Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-0004) , REPACK(64725-0004)

Revised: 7/2013

TYA Pharmaceuticals