

RULOX REGULAR - 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

• kidney disease • a magnesium-restricted diet taking a prescription drug. Antacids may interact with certain prescription drugs. symptoms last more than 2 weeks **Ask a doctor before use if you have**

Ask a doctor or pharmacist before use if you are

Stop use and ask a doctor if

Keep out of reach of children.

Directions

• shake well before use • adults and children 12 years and older: take 2 to 4 teaspoonfuls four times a day, or as directed by a doctor • do not take more than 16 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 • store at room temperature **each 5 mL teaspoonful contains:**

• 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, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

Questions or comments?

Call 1-800-645-2158, 9am -5 pm ET, Monday-Friday

RULOX REGULAR (ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE, DIMETHICONE) SUSPENSION

RULOX(COMPARE TO MAALOX) 12oz.BTL

0536-1945-83

LOT: XXXX

EXP: XX-XX-XX

MFR: RUGBY

**REPACKAGED BY: T.Y.A. PHARMACEUTICALS
2630 CRESCENT DR.
TALLAHASSEE, FL 32301
(850) 385-0228**



DOSE: SEE PACKAGE INSERT

RULOX REGULAR

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64725-1945(NDC:0536-1945)
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 HYDRO XIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL

DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL
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Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
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	MINT (mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64725-1945-1	355 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/05/2011	

Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-1945) , REPACK(64725-1945)