

ALMACONE- almacone liquid
Rebel Distributors Corp

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.

Almacone Drug Facts

Active ingredients

Aluminum Hydroxide 200mg

Magnesium Hydroxide 200mg

Keep Out of Reach of Children

Uses

Use(s)

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Uses relieves

- heartburn
- acid indigestion
- sour stomach
- gas associated with these conditions

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

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

KEEP OUT OF REACH OF CHILDREN.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Directions

Shake well before use. Do not take more than 24 teaspoonful in 24 hours or use the maximum dosage for more than 2 weeks. Adults and children 12 years and older: take 2 to 4 teaspoonsfuls between meals, at bedtime, or as directed by a doctor.

Children under 12 years: ask a doctor.

Other Information

Each 5 mL teaspoon contains:

magnesium 25 mg, sodium 1 mg. Store at room temperature. Protect from freezing. Keep tightly closed.

Inactive ingredients

Benzoyl alcohol, butylparaben, carboxy methylcellulose sodium, flavor, hypromelloses, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution.

How Supplied

Almacone (antacid) is supplied in 12 oz. bottles NDC 21695-840-12

Questions or comments?

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

Distributed by:

Rugby Laboratories

Duluth, GA 30097

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

Package/Label Principal Display Panel



ALMACONE

almacone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-840(NDC:0536-0025)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM HYDRO XIDE - UNII:NBZ3QY004S)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYL PARABEN (UNII: 3QP1U3FV8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-840-12	355 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	11/11/2008	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK