

## **ACYDONE- aluminum hydroxide, magnesium hydroxide, simethicone liquid Sigma**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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### **Active Ingredient**

Active ingredient (In each 5 ML Teaspoonful) Purpose  
Aluminium Hydroxide 200 mg Antacid  
Magnesium Hydroxide 200 mg Antacid  
Simeticone 25 mg Anti-gas

### **Indications and Usage**

COMPOSITION Each 5 ml of Suspension contains:  
Aluminum hydroxide..... 200 mg antacid  
Magnesium Hydroxide ..... 200 mg antacid  
Simethicone ..... 25 mg antifatulence

ACYDONE@ GEL is indicated in: Gastric hyperacidity of different origins, gastritis, esophagitis, flatulence, peptic ulcer, adjuvant in the treatment of gastroesophageal reflux, duodenitis, gastrointestinal disorders with excess gas.

### **Purpose**

Use For The Following:

**Relief \*Acid Indigestion \*Heartburn \* Sour Stomach \* The Symptoms referred to as gas**

### **Warning**

#### **Ask a Doctor if you have:**

Ask a Doctor if you have:

**\*kidney disease \* a magnesium restricted diet \* fever \*vomiting \* fructose intolerance**

#### **Ask a doctor or pharmacist:**

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

**Pregnant/Breastfeeding**

If pregnant or breast-feeding. Ask a health professional before use.

**Children**

keep out of reach of children

**Directions**

Shake well before use \* Adults and children 12 years of age and older: take 10 ml to 20 ml (2 to 4 teaspoonfuls) between meals, at bed time or as directed by a doctor \* Do not take more than 24 teaspoonful in 24 hours. Take Orally.

**Other Information**

Keep tightly closed \*Protect from freezing \* do not use after the expiration date \*store less than 86 ° F \* ask a doctor if symptoms persist

**Inactive Ingredients**

Sodium saccharin, Sorbitol 70%, Methylparaben, Propylparaben, flavor, Anhydrous citric acid, ethyl alcohol, Xanthan gum, Glycerine, purified water

3.9.2 CASES AND LABELS

PHARMACY PRESENTATION: LABEL X 100 ml

TAMAÑO REAL

**Acydone<sup>®</sup>  
Gel** NDC# 84831-005-01

Aluminum hydroxide  
Magnesium hydroxide  
Simethicone  
Antacid-Antiflatulent

Suspension  
100 ml  
Orally

Each 5 ml of suspension contains:  
Aluminium Hydroxide.....200 mg  
Magnesium Hydroxide.....200 mg  
Simethicone.....25 mg  
Excipients q.s.p.  
Contains: Sorbitol

Shake well before each shot

INDUSTRIA  
**SIGMA** Corp.  
QUIMICO FARMACEUTICA

Batch:  
Exp.:

110 mm

40 mm

PHARMACY PRESENTATION: CASE X 100 ml

<p><b>Acydona 100</b>          Aluminum Hydroxide          Magnesium Hydroxide          Simethicone          Antacid-Antiflatulent</p> <p>Suspension          100ml          Orally</p>	<p>5.3 cm</p>	<p><b>Acydona 100</b>          Aluminum Hydroxide          Magnesium Hydroxide          Simethicone          Antacid-Antiflatulent</p> <p>Suspension          100ml          Orally</p>	<p>5.3 cm</p>
<p><b>Acydona 100</b>          NDC# 84831-005-01</p> <p><b>Aluminum Hydroxide          Magnesium Hydroxide          Simethicone</b>          Antacid-Antiflatulent</p> <p>Suspension          100ml          Orally</p> <p>INDUSTRIA  <b>SIGMA</b> Corp.          QUIMICO FARMACEUTICA</p>	<p>Each 5 ml of suspension contains:          Aluminum Hydroxide ..... 200 mg          Magnesium Hydroxide ..... 200mg          Simethicone ..... 25 mg          Excipients q.s.m.          contains sorbitol</p> <p>Sanitary Reg.: NN-49057/2018</p> <p>EXP.</p> <p>BATCH</p>	<p><b>Acydona 100</b>          Aluminum Hydroxide          Magnesium Hydroxide          Simethicone          Antacid-antiflatulent</p> <p>Suspension          100ml          Orally</p> <p>INDUSTRIA  <b>SIGMA</b> Corp.          QUIMICO FARMACEUTICA</p>	<p>Dosage          See attached brochure.          Shake well before each shot.</p> <p>Keep out of the reach of children          Store in a cool and dry place, at a          temperature not higher than 30° C.          Protected from light          Dispensed under medical prescription</p> <p></p> <p>Pharmaceutical Regent:          Dr. Betty G. Paz Fernandez          Biochemistry - Pharmaceutical</p> <p>INDUSTRIA  <b>SIGMA</b> Corp.          QUIMICO FARMACEUTICA          Parque Industrial Suroccidental A.M. III          Cochabamba - Bolivia</p>

13 cm

Interior leaflet

## ACYDONE® GEL

Aluminum Hydroxide - Magnesium Hydroxide - Simethicone  
Antacid - Antiflatulent

### COMPOSITION

Each 5 ml of Suspension contains: Aluminum hydroxide..... 200 mg Magnesium Hydroxide ..... 200 mg  
Simethicone ..... 25 mg Excipients qs . Contains sorbitol.

### INDICATIONS

ACYDONE® GEL is indicated in: Gastric hyperacidity of different origins, gastritis, esophagitis, flatulence, peptic ulcer, adjuvant in the treatment of gastroesophageal reflux, duodenitis, gastrointestinal disorders with excess gas.

### ROUTE OF ADMINISTRATION AND DOSAGE

 Orally

Adult Dosage: Take 15-30 ml (1 to 2 tablespoons), 1 to 3 hours after meals and at bedtime.

### TREATMENT DURATION

It should not be taken for more than two weeks, except under medical supervision.

### CONTRAINDICATIONS

It should not be administered to patients with renal insufficiency. Do not use it in cases of fever and vomiting.

Hypersensitivity to any component of the drug.

### PRECAUTIONS

Appendicitis, diverticulitis, ileostomy, gastric and/or intestinal obstruction.

It should be taken into account that ACYDONE® GEL contains 3.9 g of Sorbitol/15ml, it could cause stomach discomfort and diarrhea. It should not be used in patients with hereditary fructose intolerance.

### SIDE EFFECTS

Diarrhea from magnesium or constipation from aluminum, nausea, vomiting. For prolonged use: loss of appetite, continuous headache, bone pain.

### INTERACTIONS

In general, the product may interact with the following drugs: Digoxin, indomethacin, salicylates, INH, ciprofloxacin, chlorpromazine, benzodiazepines, warfarin, levodopa, beta-adrenergic blockers, tetracyclines, nitrofurantoin, ketoconazole, H2 blockers, pyrimethamine, quinidine, xanthines.

Interactions are minimized by administering the suspension and any other drug within 2-3 hours of each other.

### POISONING

No cases of overdose have been reported.

PRESENTATION Oral suspension in a bottle of 100 ml.

### ACYDONE GEL STORAGE

Store in a cool and dry place, at a temperature not exceeding 30°C. Protected from light.

- ✓ OVER-THE-COUNTER MEDICATION. THIS MEDICATION SHOULD NOT BE USED AFTER THE EXPIRY DATE.
- ✓ UNLESS PRECISELY INDICATED BY THE DOCTOR SHOULD NOT BE USED ANY MEDICATION DURING PREGNANCY.
- ✓ MEDICATIONS SHOULD BE KEPT OUT OF THE REACH OF CHILDREN. SEE A DOCTOR IF SYMPTOMS PERSIST OR WORSE

Produced by:



aluminum hydroxide, magnesium hydroxide, simethicone liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84831-005
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	25 mg in 5000 mg
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5000 mg
<b>MAGNESIUM HYDROXIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	200 mg in 5000 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	1 mg in 5000 mg
<b>MINT</b> (UNII: FV98Z8GITP)	0.25 mg in 5000 mg
<b>ALCOHOL</b> (UNII: 3K9958V90M)	40 mg in 5000 mg
<b>WATER</b> (UNII: 059QF0KO0R)	3558.3 mg in 5000 mg
<b>CHERRY</b> (UNII: BUC5I9595W)	2.5 mg in 5000 mg
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	500 mg in 5000 mg
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	0.45 mg in 5000 mg
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	5 mg in 5000 mg
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	17.5 mg in 5000 mg
<b>SORBITOL</b> (UNII: 506T60A25R)	400 mg in 5000 mg
<b>SODIUM SACCHARIN</b> (UNII: SB8ZUX40TY)	50 mg in 5000 mg

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY, MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84831-005-01	5000 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/11/2024	

**Labeler -** Sigma (815366311)

### Establishment

Name	Address	ID/FEI	Business Operations
INDUSTRIA QUIMICO FARMACEUTICA SIGMA CORP. S.R.L.		815366311	manufacture(84831-005)

Revised: 11/2024

Sigma