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.

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

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

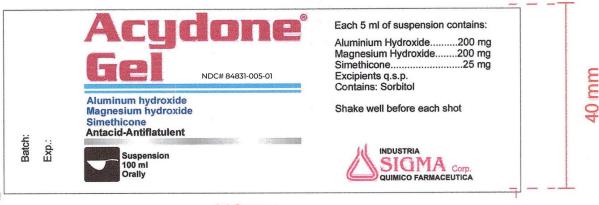
Keep tightly closed *Protect from feezing * do not use after the expiration date *store less than 86 $^{\circ}$ F * ask a doctor if symptoms persist

Inactive Ingredients

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

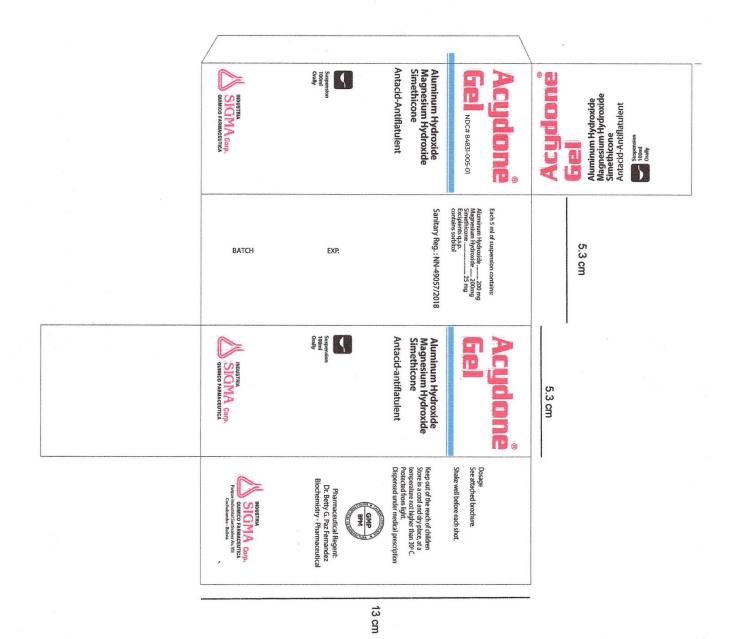
PHARMACY PRESENTATION: LABEL X 100 ml

TAMAÑO REAL



110 mm

PHARMACY PRESENTATION: CASE X 100 ml



ACYDONE® GEL

Aluminum Hydroxide - Magnesium Hydroxide - Simethicone Antacid - Antiflatulent

COMPOSITION

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.
- V UNLESS PRECISELY INDICATED BY THE DOCTOR SHOULD NOT BE USED ANY MEDICATION DURING
- V PREGNANCY.
- $_{ee}$ 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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84831-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	25 mg in 5000 mg	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	200 mg in 5000 mg	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	200 mg in 5000 mg	

Inactive Ingredients				
Ingredient Name	Strength			
PROPYLPARABEN (UNII: Z8IX2SC10H)	1 mg in 5000 mg			
MINT (UNII: FV98Z8GITP)	0.25 mg in 5000 mg			
ALCOHOL (UNII: 3K9958V90M)	40 mg in 5000 mg			
WATER (UNII: 059QF0KO0R)	3558.3 mg in 5000 mg			
CHERRY (UNII: BUC5I9595W)	2.5 mg in 5000 mg			
GLYCERIN (UNII: PDC6A3C0OX)	500 mg in 5000 mg			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.45 mg in 5000 mg			
METHYLPARABEN (UNII: A2I8C7HI9T)	5 mg in 5000 mg			
XANTHAN GUM (UNII: TTV12P4NEE)	17.5 mg in 5000 mg			
SORBITOL (UNII: 506T60A25R)	400 mg in 5000 mg			
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	50 mg in 5000 mg			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor	CHERRY, MINT	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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