REGULAR STRENGTH ANTACID- aluminum hydroxide, magnesium hydroxide, dimethicone suspension CVS

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.

CVS ANTACID original

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

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

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

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

- each 5 mL teas poonful contains: magnesium 85 mg, sodium 3 mg
- store at room temperature

- protect from freezing
- keep tightly closed

Inactive ingredients

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

Questions or comments?

1-800-540-3765

package Label

CVS Health

COMPARE TO THE ACTIVE INGREDIENTS IN MYLANTA® REGULAR STRENGTH*
REGULAR STRENGTH

Antacid

Liquid

Alumina / Magnesia / Simethicone

Antacid/Anti-gas

Fast-Acting

Soothing Relief of:

- Heartburn
- Acid Indigestion
- Sour Stomach

Plus anti-gas relief ORIGINAL FLAVOR

Alcohol: less than 0.5% 12 FL OZ (355 mL)



Compare to the active ingredients in Mylanta® Regular Strength*

Regular Strength

Antacid Liquid

ALUMINA / MAGNESIA / SIMETHICONE Antacid/Anti-gas

Fast-Acting

Soothing relief of:

- Heartburn
- Acid indigestion
- Sour stomach

Plus anti-gas relief

Original Flavor Alcohol: Less than 0.5%

12 FLOZ (355 mL) 205-06112-1 REV GC-0615

Drug Facts TAMPER-EVIDENT: DO NOT USE IF BREAKAWAY BAND ON BOTTLE CAP IS MISSING OR BROKEN.

Active ingredients (in each 5 mL teaspoonful)

Purposes

Aluminum hydroxide 200 mg (equivalent to dried gel, USP)Antacid Magnesium hydroxide 200 mg Antacid Simethicone 20 mg Antigas

Uses relieves • heartburn

- · acid indigestion · the symptoms referred to as gas

Warnings

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kidney disease
 magnesium-restricted diet

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Questions or comments? 1-800-540-3765

*This product is not manufactured or distributed by J & J • MERCK Consumer Pharmaceuticals Co., distributor of Mylanta®.

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REGULAR STRENGTH ANTACID

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

HUMAN OTC DRUG NDC:69842-286 Product Type Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AT LIMINIUM LIVED O VIDE (LINIU, EO DOTTUINIO) (AT LIMINIUM LIVED O VIDE LINIU, EO DOTTUINIO)	ALUMINUM	200 mg

ALUMINUM III DAO AIDE (UMI. OQDU IZIOMU) (ALUMINUM III DAO AIDE - UMI.OQDU IZIOM	HYDRO XIDE	in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838 HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:69842-286-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/01/2015	

Labeler - CVS (062312574)

Registrant - GCP Laboratories (965480861)

Establishment			
Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(69842-286), pack(69842-286)

Revised: 12/2017 CVS