MYLANTA MAXIMUM STRENGTH CLASSIC FLAVOR- antacid and anti gas aluminum hydroxide magnesium hydroxide and simethicone suspension Infirst Healthcare Inc.

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.

Mylanta Maximum Strength Classic Flavor 3.4 FL OZ

Active ingredients (in each 2 tsp dose)

Aluminum hydroxide (equivalent to dried gel, USP) 800 mg Magnesium hydroxide 800 mg

Simethicone 80 mg

Purpose

Antacid

Antacid

Anti-gas

Uses

relieves:

- heartburn
- acid indigestion
- sour stomach
- upset stomach due to these symptoms
- pressure and bloating commonly referred to as gas
- overindulgence in food and drink

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

presently taking a prescription drug. Antacids may interact with certain prescription drugs.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions

- shake well before use
- adults and children 12 years and over:

2 tsp - 4 tsp (1-2 doses) between meals, at bedtime or as directed by a doctor

- do not take more than 12 tsp (6 doses) in any 24-hour period
- do not use the maximum dosage for more than 2 weeks
- children under 12 years: ask a doctor
- tsp = teaspoon

Other information

- each 2 tsp dose contains: magnesium 340 mg; sodium 7 mg
- store between 20-25°C (68-77°F), do not freeze

Inactive ingredients

benzyl alcohol, carboxymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, purified water, sodium carbonate, sorbitol, sucralose, xanthan gum

Questions or comment?

call **1-844-695-6624** toll free (English and Spanish)

Principal Display Panel

MYLANTA®

ANTACID

+

ANTI-GAS

Alcohol 0.2%

MAXIMUM STRENGTH

FAST HEARTBURN & GAS RELIEF ON THE GO!

SMOOTH CREAMY TASTE

CLASSIC

FLAVOUR

3.4 FL OZ (100 mL)

78034MYLLF

TAMPER-EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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infirst+

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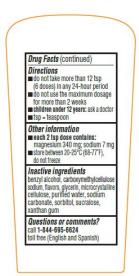
Mylanta.com

Manufactured for: Infirst Healthcare Inc. Westport, CT 06880









MYLANTA MAXIMUM STRENGTH CLASSIC FLAVOR

antacid and anti gas aluminum hydroxide magnesium hydroxide and simethicone suspension

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62372-500 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|---|------------------------|--------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0) | ALUMINUM HYDROXIDE | 800 mg in 10 mL | |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM HYDROXIDE | 800 mg in 10 mL | |
| DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) | DIMETHICONE | 80 mg in 10 mL | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | | | |
| SORBITOL (UNII: 506T60A25R) | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | |

| Product Characteristics | | | |
|-------------------------|-------------------|--------------|--|
| Color | WHITE (OFF WHITE) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:62372- 500-10 | 100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/01/2020 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part331 | 11/10/2016 | |
| | | | |

Labeler - Infirst Healthcare Inc. (079159739)

Revised: 2/2023 Infirst Healthcare Inc.