MINTOX- aluminum hydroxide, magnesium hydroxide, dimethicone suspension A-S Medication Solutions

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.

maj mintox

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
- 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 of age and older: take 2 to 4 teaspoonfuls between meals, at bedtime, or as directed by a doctor
- do not take more than 16 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 teaspoonful contains: magnesium 85 mg, sodium 3 mg
- store at room temperature and avoid freezing
- keep tightly closed

Inactive ingredients

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

HOW SUPPLIED

Product: 50090-1538

NDC: 50090-1538-0 355 mL in a BOTTLE

aluminum hydroxide, magnesium hydroxide, dimethicone



MINTOX

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

| Product | Туре |
|---------|------|
|---------|------|

Route of Administration ORAL

| Active Ingredient/Active Moiety | | | | |
|--|-------------------------|-------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0) | ALUMINUM HYDROXIDE | 200 mg in 5 mL | | |
| MAGNESIUM HYDROXIDE (UNII: NBZ 3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P) | MAGNES IUM HYDROXIDE | 200 mg in 5 mL | | |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 20 mg in 5 mL | | |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| BUTYLPARABEN (UNII: 3QPI1U3FV8) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SORBITOL (UNII: 506T60A25R) | |
| | |

| Product Characteristics | | | |
|-------------------------|------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
|-------------------------------|---|-------------------------|-----------------------|
| 1 NDC:50090- 1538-0 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2014 | |
| | | | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part331 | 02/01/2011 | | |

| Establishment | | | | |
|--------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| A-S Medication Solutions | | 830016429 | RELABEL(50090-1538) | |

Revised: 9/2021

A-S Medication Solutions