

HEALTHY ACCENTS MALDROXAL- aluminum hydroxide, magnesium hydroxide, simethicone suspension

DZA Brands LLC

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.

DZA Brands, LLC Maldroxal® Drug Facts

Active ingredients (in each 10 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 800 mg

Magnesium hydroxide 800 mg

Simethicone 80 mg

Purpose

Antacid

Antigas

Uses

for the relief of

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms
- pressure and bloating commonly 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

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

When using this product

do not take more than 40 mL in a 24-hour period, or use the maximum dosage for more than 2 weeks, except under the advice and supervision of a physician

Keep out of reach of children.

Directions

- shake well before using
- only use the dose cup provided
- adults and children 12 years and older: take 10 mL to 20 mL two times a day or as directed by a physician
- do not take more than 40 mL in 24 hours or use the maximum dosage for more than 2 weeks
- children under 12 years: consult a physician

Other information

- each 10 mL contains: magnesium 350 mg and sodium 3 mg
- does not meet USP requirements for preservative effectiveness
- store at 20-25°C (68-77°F)
- protect from freezing

Inactive ingredients

butylparaben, flavor, glycerin, hydroxyethyl cellulose, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol, sorbitol solution

Questions or comments?

1-866-322-2439

Principal Display Panel

advanced maximum strength

maldroxal® antacid plus antigas

fast soothing relief of:

heartburn

acid indigestion

pressure & bloating (gas)

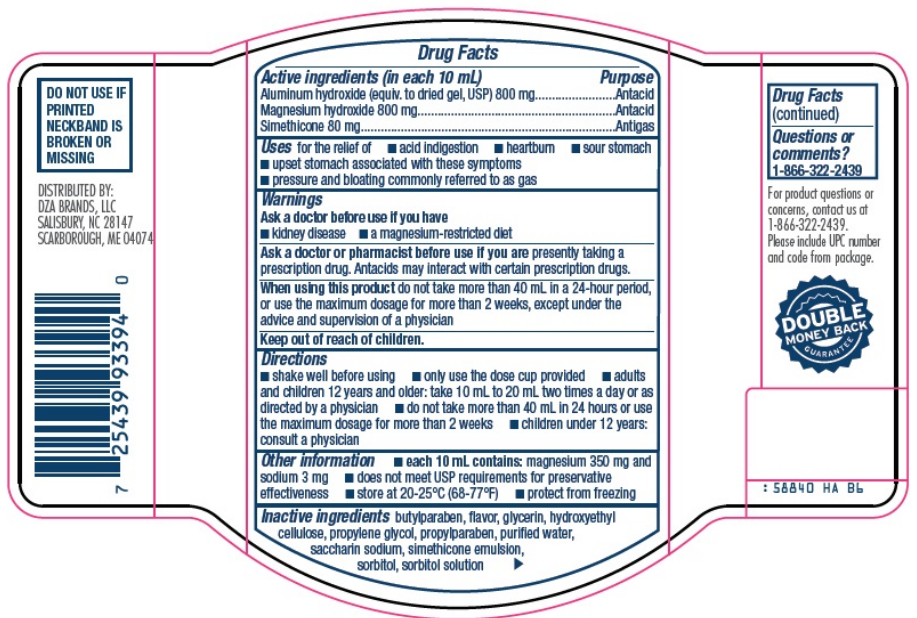
Compare to Maalox® Advanced Maximum Strength active ingredients

cherry flavor

ALCOHOL 0.1%

12 FL OZ (355 mL)

NO GLUTEN



HEALTHY ACCENTS MALDROXAL

aluminum hydroxide, magnesium hydroxide, simethicone suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55316-588 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|-----------------|
| ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0) | ALUMINUM HYDRO XIDE | 800 mg in 10 mL |
| MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159UV381P) | MAGNESIUM HYDRO XIDE | 800 mg in 10 mL |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 80 mg in 10 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------|----------|
| BUTYLPARABEN (UNII: 3QPII03FV8) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SORBITOL (UNII: 506T60A25R) | |
| SILICON DIO XIDE (UNII: ETJ7Z6XBU4) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|--|
| Color | WHITE (opaque) | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55316-588-40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/22/2008 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part332 | 01/22/2008 | |

Labeler - DZA Brands LLC (090322194)

Revised: 12/2018

DZA Brands LLC