MAG-AL PLUS- aluminum hydroxide, magnesium hydroxide, and simethicone suspension PAI Holdings, LLC

Mag-AL Plus

Drug Facts

| Active ingredients (in each $5 \text{ mL} = 1 \text{ teaspoonful}$) | Purpose |
|--|---------|
| Aluminum hydroxide (equiv. to dried gel, USP) 200 mg | Antacid |
| Magnesium hydroxide 200 mg | Antacid |
| Simethicone 20 mg | Antigas |

Uses

for the relief of:

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

Warnings

Do not take more than 16 teaspoonfuls in a 24-hour period or use the maximum dosage for more than 2 weeks except under the advice and supervision of a physician.

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.

Stop use and ask a doctor if symptoms last more than 2 weeks.

Keep out of reach of children.

Directions

- shake well before using
- do not take more than 16 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks

Other information

- each 5 mL contains: magnesium 83 mg, sodium 1.34 mg
- store at controlled room temperature 20° 25°C (68° 77°F)
- protect from freezing
- White colored, peppermint flavored liquid supplied in the following oral dosage form:

NDC 0121-1761-30: 30 mL unit dose cup. Case contains 100 unit dose cups of 30

mL packaged in 10 trays of 10 unit dose cups each.

Inactive ingredients

Butylparaben, hydroxypropyl methylcellulose, flavoring, propylene glycol, propylparaben, purified water, sodium saccharin, and sorbitol solution.

Questions or comments?

Call 1-800-845-8210

MANUFACTURED BY

Pharmaceutical Associates, Inc.

Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 30 mL Unit-Dose Cup Tray Label

Delivers 30 mL

NDC 0121-1761-30

MAG-AL PLUS

Each 30 mL contains:

Aluminum Hydroxide 1200 mg

Magnesium Hydroxide 1200 mg

Simethicone 120 mg

SHAKE WELL

USUAL DOSAGE: See attached Drug Facts

Package Not Child-Resistant

Pharmaceutical Associates, Inc.

Greenville, SC 29605



MAG-AL PLUS

aluminum hydroxide, magnesium hydroxide, and simethicone suspension

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0121-1761 |
| 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: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P) | MAGNESIUM HYDROXIDE | 200 mg in 5 mL | |
| DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) | DIMETHICONE | 20 mg in 5 mL | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| BUTYLPARABEN (UNII: 3QPI1U3FV8) | | | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | | | |
| HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN31520P35) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| SORBITOL (UNII: 506T60A25R) | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | | | |
| WATER (UNII: 059QF0KO0R) | | | |

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

| P | Packaging | | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:0121- 1761-30 | 10 in 1 CASE | 01/14/2004 | | | |
| 1 | | 10 in 1 TRAY | | | | |
| 1 | | 30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product | | | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M001 | 01/14/2004 | |
| | | | |

Labeler - PAI Holdings, LLC (044940096)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|----------------------------|
| PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma | | 097630693 | manufacture(0121- 1761) |

Revised: 12/2022 PAI Holdings, LLC