

**MAG-AL PLUS XS- aluminum hydroxide, magnesium hydroxide, and dimethicone suspension**  
**PAI Holdings, LLC**

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**Mag-AL Plus XS**

***Drug Facts***

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***Active ingredients (in each 5 mL = 1 teaspoonful) Purpose***

|  |         |
|--|---------|
| Aluminum hydroxide (equiv. to dried gel, USP) 400 mg | Antacid |
| Magnesium hydroxide 400 mg                           | Antacid |
| Simethicone 40 mg                                    | Antigas |

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***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 8 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 8 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks
-

adults and children 12 years and older

take 2 to 4 teaspoonfuls two times a day or  
as directed by a physician

children under 12 years

consult a physician

### **Other information**

- **each 5 mL contains:** magnesium 167 mg, sodium 2.24 mg
- store at controlled room temperature 20° - 25°C (68° - 77°F) [see USP Controlled Room Temperature].
- protect from freezing
- White colored, cherry flavored liquid supplied in the following oral dosage form:

NDC 0121-1762-30: 30 mL unit dose cup. Case contains 100 unit dose cups of 30 mL packaged in 10 trays of 10 unit dose cups each.

\*Maalox is a registered trademark of Novartis Consumer Health, Inc.

### ***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  
www.paipharma.com

### **PRINCIPAL DISPLAY PANEL - 30 mL Cup Tray Label**

Delivers **30 mL**

**NDC 0121-1762-30**

**MAG-AL PLUS XS**

Each 30 mL contains:

Magnesium Hydroxide 2400 mg

Aluminum Hydroxide 2400 mg

Simethicone 240 mg

**SHAKE WELL**

**Package Not Child-Resistant**

Pharmaceutical Associates, Inc.  
Greenville, SC 29605

See Insert



## MAG-AL PLUS XS

aluminum hydroxide, magnesium hydroxide, and dimethicone suspension

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0121-1762 |
| Route of Administration | ORAL           |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of | Strength |
|-----------------|----------|----------|
|-----------------|----------|----------|

| Ingredient Name   | Strength            | Strength       |
|---|---------------------|----------------|
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)                                 | ALUMINUM HYDROXIDE  | 400 mg in 5 mL |
| <b>MAGNESIUM HYDROXIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P) | MAGNESIUM HYDROXIDE | 400 mg in 5 mL |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)   | DIMETHICONE         | 40 mg in 5 mL  |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)                   |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                  |          |
| <b>HYPROMELLOSE 2910 (4000 MPA.S)</b> (UNII: RN3152OP35) |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)               |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)                       |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)               |          |
| <b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)                 |          |
| <b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)               |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                          |          |

### Product Characteristics

|                 |        |                     |  |
|-----------------|--------|---------------------|--|
| <b>Color</b>    | white  | <b>Score</b>        |  |
| <b>Shape</b>    |        | <b>Size</b>         |  |
| <b>Flavor</b>   | CHERRY | <b>Imprint Code</b> |  |
| <b>Contains</b> |        |                     |  |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0121-1762-30 | 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 | M002                                     | 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(0121-1762) |
|--|--|-----------|------------------------|

Revised: 8/2022

PAI Holdings, LLC