

GELFOS-M- aluminum phosphate, colloidal, magnesium hydroxide, simethicone liquid
LYDIA Co., Ltd

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.

Aluminum Phosphate, Colloidal

Magnesium Hydroxide

Simethicone

- sour stomach ■ acid indigestion ■ upset stomach associated with these

Keep out of reach of children

- take 2-3 envelopes as symptoms occur, as directed by a doctor

Warnings

Ask a doctor before use if you have taking a prescription drug. Antacids may interact with certain prescription drugs

When using this product

- Do not take more than 4 envelope in 24 hours
- Do not use the maximum dosage for more than 2 weeks

water, sugar, agar, pectin, essence of orange, calcium

For oral use only

GELFOS-M

| | |
|---|----------------|
| Drug Facts | |
| Active Ingredients (in 20g) | Purpose |
| Aluminum Phosphate, Colloidal 12.38g/20g | Antacid |
| Magnesium Hydroxide 400mg/20g | Antacid |
| Simethicone 40mg/20g | Deqas |
| Uses | |
| ■ sour stomach ■ acid indigestion ■ upset stomach associated with these | |
| Warnings | |
| Ask a doctor before use if you have taking a prescription drug. Antacids may interact with certain prescription drugs | |
| When using this product | |
| ■ Do not take more than 4 envelope in 24 hours | |
| ■ Do not use the maximum dosage for more than 2 weeks | |
| Keep out of reach of children | |
| Directions | |
| ■ take 2-3 envelopes as symptoms occur, as directed by a doctor | |
| Other Information | |
| ■ Store at room temperature | |
| Inactive Ingredient | |
| water, sugar, agar, pectin, essence of orange, calcium | |
| Questions or comments ? | |
| Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405 | |
| Distributed By: P&K FRONTIER MARKETING CORP. | |
| 329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA | |
| Made in South Korea | |

GELFOS-M

aluminum phosphate, colloidal, magnesium hydroxide, simethicone liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72988-0017 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|--------------------|
| ALUMINUM PHOSPHATE (UNII: F92V3S521O) (ALUMINUM PHOSPHATE - UNII:F92V3S521O) | ALUMINUM PHOSPHATE | 12.38 g in 20 g |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P) | MAGNESIUM HYDROXIDE | 400 mg in 20 g |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 40 mg in 20 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------|----------|
| PECTIN (UNII: 89NA02M4RX) | |
| WATER (UNII: 059QF0KO0R) | |
| AGAR (UNII: 89T13OHQ2B) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72988-0017-1 | 4 in 1 PACKAGE | 10/08/2019 | |
| 1 | | 20 g in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331 | 10/08/2019 | |

Labeler - LYDIA Co., Ltd (695735569)

Registrant - LYDIA Co., Ltd (695735569)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|-------------------------|
| I World Pharmaceutical Co., Ltd | | 688222857 | manufacture(72988-0017) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|---------------------|
| LYDIA Co., Ltd | | 695735569 | label(72988-0017) |

Revised: 10/2019

LYDIA Co., Ltd