**MAXIMUM STRENGTH GAS RELIEF- simethicone capsule, liquid filled**
**CVS PHARMACY, INC.**

*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.*

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**SIMETHICONE CAPSULES 250 mg, liquid filled**

**Active ingredient (in each softgel)**

Simethicone 250 mg

**Purpose**

Anti-gas

**Use**

- relieves bloating, pressure or fullness commonly referred to as gas

**Warnings**

**Stop use and ask a doctor if**

condition persists

**Keep out of reach of children.**

**Directions**

- swallow one or two softgels after a meal
- do not exceed two softgels per 24 hours except under the advice and supervision of a physician

**Other information**

- store at room temperature 59°-86°F (15°-30°C)

**Inactive ingredients**

D&C red #33, FD&C blue #1, gelatin, glycerin, purified water, and white edible ink

**Questions or Comments?**

Call toll free: **1-855-215-8180**

**PRINCIPAL DISPLAY PANEL**

CVS MAXIMUM STRENGTH GAS RELIEF

SIMETHICONE 250 mg

Anti-gas

NDC 69842-068-04

Compare to the active ingredient in PHAZYME® Maximum Strength

24 Liquid-Filled SoftGels


CVS MAXIMUM STRENGTH GAS RELIEF

SIMETHICONE 250 mg

Anti-gas

NDC 69842-068-22

Compare to the active ingredient in PHAZYME® Maximum Strength

60 Liquid-Filled SoftGels


# MAXIMUM STRENGTH GAS RELIEF

simethicone capsule, liquid filled

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69842-068 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 250 mg |

| Inactive Ingredients | |
|---|---|
| Ingredient Name | Strength |
| **D&C RED NO. 33** (UNII: 9DBA0SBB0L) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | purple | **Score** | no score |
| **Shape** | capsule (oval) | **Size** | 13mm |
| **Flavor** | | **Imprint Code** | PC31 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69842-068-04 | 2 in 1 CARTON | 12/13/2016 | |
| **1** | | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:69842-068-22 | 1 in 1 CARTON | 12/13/2016 | |
| **2** | | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part332 | 12/13/2016 | |

## Labeler - CVS PHARMACY, INC. (062312574)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd. | | 421293287 | manufacture(69842-068) , analysis(69842-068) |

Revised: 12/2016 CVS PHARMACY, INC.