ULTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled RELIABLE 1 LABORATORIES 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.

Ultra Strength Gas Relief

Drug Facts

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Anti-gas

Uses

• 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 1 or 2 softgels as needed after a meal
- do not exceed two softgels per day except under the advice and supervision of a physician

Other information

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

Inactive ingredients

FD&C yellow#6, gelatin, glycerin, purified water and white edible ink

Questions or comments?

Call: 516-341-0666

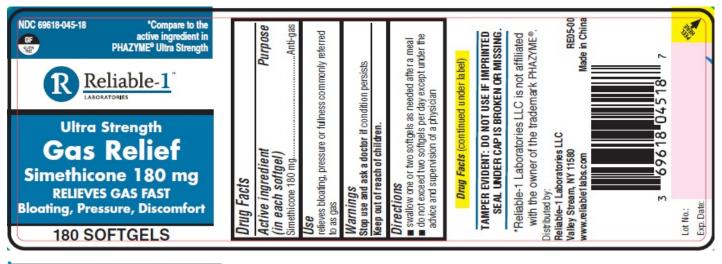
PRINCIPAL DISPLAY PANEL

Ultra Strength Gas Relief

Simethicone 180 mg Anti-gas 180 Softgels

NDC 69618-045-18

*Compare to the active ingredient in PHAZYME[®] Ultra Strength



| Drug Facts (continued) 4 Other information 1000000000000000000000000000000000000 |
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ULTRA STRENGTH GAS RELIEF

| HUMAN OTC DRUG | Item Code (Sour | NDC:69618-045 | | |
|--|--|---|---|--|
| ORAL | | | | |
| | | | | |
| oiety | | | | |
| | | | | Strength |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | | | Έ | 180 mg |
| | | | | |
| | | | | |
| Ingredient Name | | | Strength | |
| EI93A8) | | | | |
| | | | | |
| | | | | |
| | | | | |
| | HUMAN OTC DRUG ORAL oiety ngredient Name) (DIMETHICONE - UNII:92RU3N3 | HUMAN OTC DRUG Item Code (Sourd ORAL ORAL | HUMAN OTC DRUG Item Code (Source) ORAL ORAL | HUMAN OTC DRUG Item Code (Source) NDC:6961 ORAL ORAL |

| Product Characteristics | | | | | | | |
|--|----------------------------|------------|-----------------------------|---------------------|--|--|--|
| Color | orange (clear) | Score | | no score | | | |
| Shape | capsule (oval) | Size | | 10 mm | | | |
| Flavor | | Imprint Co | de | PC3 | | | |
| Contains | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | Package Description | | Marketing Start Date | Marketing End Date | | | |
| " Item Code | I uchage De | escription | Marketing Start Date | Marketing Life Date | | | |
| n n n 1 NDC:69618-045-18 | | • | 07/13/2017 | Marketing Life Date | | | |
| | | • | | Marketing Life Date | | | |
| | | • | | | | | |
| | 180 in 1 BOTTLE; Type 0: N | • | | | | | |
| 1 NDC:69618-045-18 | 180 in 1 BOTTLE; Type 0: N | • | | Marketing End Date | | | |

Labeler - RELIABLE 1 LABORATORIES LLC (079718111)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|---|
| Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd. | | 421293287 | manufacture(69618-045), analysis(69618-045) |

Revised: 7/2017

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