**SIMETHICONE CERTIFIED PLUS- simethicone gel**
**Advance Pharmaceutical 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.*

---

**Certified Plus Anti-Gas SIMETHICONE 180 MG**

## Active Ingredient

Simethicone 180 mg

## Purpose

Antiflatulent

## Uses

relieves

- bloating
- pressure
- fullness commonly referred to as gas

## Warnings

**If pregnant or breast-feeding,** ask a health professional before use.

## Keep out of reach of children

## Directions

- swallow 1 to 2 softgels as needed after meals and at bed time.
- do not exceed 6 tablets per day unless directed by a physician

## Other Information

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

## Inactive Ingredients

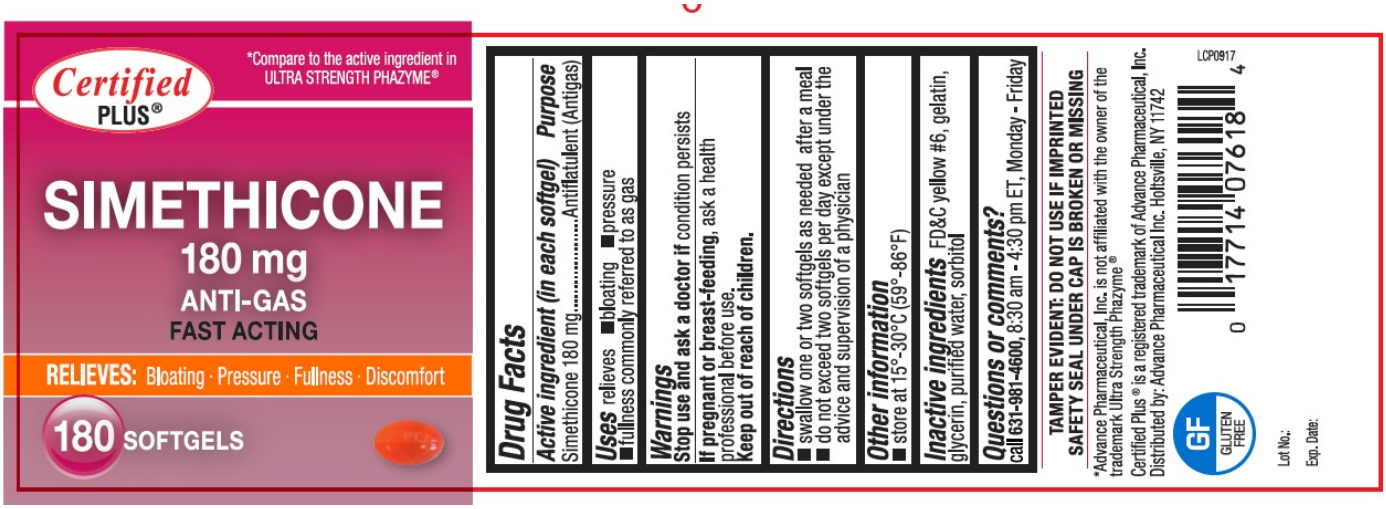
FD&C Yellow #6, gelatin, glycerin, purified water, sorbitol

## Questions or Comments

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Call 631-981-4600, 8.30 am – 4.30 pm EST Monday - Friday**

## Package Label




# SIMETHICONE CERTIFIED PLUS

simethicone gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:17714-076 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 180 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | orange | **Score** | |
| **Shape** | OVAL | **Size** | 3mm |
| **Flavor** | | **Imprint Code** | PC3 |

| Contains | |
|---|---|

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:17714-076-18 | 180 in 1 BOTTLE; Type 0: Not a Combination Product | 11/11/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part332 | 11/11/2021 | |

## Labeler - Advance Pharmaceutical Inc. (078301063)

## Registrant - Advance Pharmaceutical Inc. (078301063)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Advance Pharmaceutical Inc. | | 078301063 | manufacture(17714-076) |

Revised: 11/2021 Advance Pharmaceutical Inc.