

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

Certified PLUS®
 *Compare to the active ingredient in ULTRA STRENGTH PHAZYME®

SIMETHICONE
 180 mg
 ANTI-GAS
 FAST ACTING

RELIEVES: Bloating · Pressure · Fullness · Discomfort

180 SOFTGELS

Drug Facts
Active ingredient (in each softgel) Purpose
 Simethicone 180 mg.....Antiflatulent (Antigas)

Uses relieves ■ bloating ■ pressure
 ■ fullness commonly referred to as gas

Warnings
 Stop use and ask a doctor if condition persists if pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

Directions
 ■ swallow one or two 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 15°-30°C (59°-86°F)

Inactive ingredients FD&C yellow #6, gelatin, glycerin, purified water, sorbitol

Questions or comments?
 call 631-981-4600, 8:30 am - 4:30 pm ET, Monday - Friday

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

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GF
 GLUTEN FREE

Lot No.:
 Exp. Date:

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.