

SIMETHICONE- simethicone tablet, chewable
Aphena Pharma Solutions - Tennessee, LLC

GAS RELIEF SIMETHICONE

Drug Facts

Active Ingredient

(in each chewable tablet)

Simethicone 80 mg

Purpose

Antiflatulent

Uses

relieves

- bloating
- pressure
- discomfort of gas which can be caused by certain foods or air swallowing

Warnings

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

Keep out of reach of children

Directions

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

Other Information

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

Inactive Ingredients

dextrose, dipac sugar, maltodextrin, peppermint flavor, sorbitol, stearic acid

Questions or Comments

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

Call 804-270-4498, 8.30 am - 4.30 pmEST Monday - Friday

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	80 mg
4	71610-607-04

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20211105JH

PRINCIPAL DISPLAY PANEL - 80 mg

NDC 71610-607 - Simethicone 80 mg Chewable Tablets

Simethicone

80mg 4 Chewable Tablets

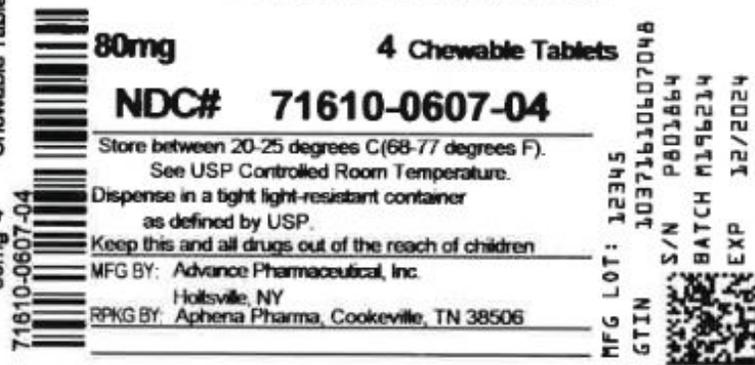
NDC# 71610-0607-04

Store between 20-25 degrees C (68-77 degrees F).
See USP Controlled Room Temperature.
Dispense in a tight light-resistant container
as defined by USP.
Keep this and all drugs out of the reach of children

MFG BY: Advance Pharmaceutical, Inc.
Holtsville, NY
RPKG BY: Aphenra Pharma, Cookeville, TN 38506

Simethicone
80mg 4
Chewable Tablets
71610-0607-04

MFG LOT: 12345
GTIN 30371610607048
S/N P803664
BATCH M196214
EXP 12/2024



SIMETHICONE

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-607(NDC:54738-518)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE (UNII: IY9XDZ35W2)	
SUCROSE (UNII: C151H8M554)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEPPERMINT (UNII: V95R5KMY2B)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	AP;019
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-607-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	03/01/2011	

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	repack(71610-607)

Revised: 1/2025

Aphenia Pharma Solutions - Tennessee, LLC