SIMETHICONE- simethicone tablet, chewable
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.

GAS RELIEF SIMETHICONE 125 MG

Active Ingredient

(in each chewable tablet)

Simethicone 125 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 physician

Other Information

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

Inactive Ingredients

dextrose, dipac sugar, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide, sorbitol, stearic acid

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

NDC: 17714-040-60 – 60 CHEWABLE TABLETS

SIMETHICONE

simethicone tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DEXTROSE (UNII: IY9XDZ35W2)	
SUCROSE (UNII: C151H8M554)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEPPERMINT (UNII: V95R5KMY2B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	16mm

Flavor	PEPPERMINT	**Imprint Code**	AP;040
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17714-040-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	11/01/2012	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-040)

Revised: 12/2018 Advance Pharmaceutical Inc.