GAS RELIEF- 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

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 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

Package Label

DC: 17714-019-01 - 100 CHEWABLE TABLETS



GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17714-019

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthDIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)DIMETHICONE80 mg

Inactive Ingredients				
Ingredient Name	Strength			
DEXTROSE (UNII: IY9 XDZ35W2)				
SUCROSE (UNII: C151H8 M554)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				
PEPPERMINT (UNII: V95R5KMY2B)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
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	M	larketing Start Date	Marketing End Date		
1 NDC:17714-019-01	100 in 1 BOTTLE; Type 0: Not a Combination	on Product 11/	/04/1999			
Marketing Information						
Marketing Categor	y Application Number or Monograp	h Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part332	11	1/04/1999			

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment					
Name	Address	ID/FEI	Business Operations		
Advance Pharmaceutical Inc.		078301063	manufacture(17714-019)		

Revised: 12/2018 Advance Pharmaceutical Inc.