

**SIMETHICONE- simethicone tablet, chewable**  
**Richmond Pharmaceuticals, 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.*

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**GAS RELIEF SIMETHICONE**

**Drug Facts**

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**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 pm EST Monday - Friday

**Package Label**

**NDC: 54738-518-01**

**– 100 CHEWABLE**



**TABLETS**

<b>SIMETHICONE</b>			
simethicone tablet, chewable			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54738-518
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	80 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
DEXTROSE (UNII: IY9XDZ35W2)			
SUCROSE (UNII: C151H8M554)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
PEPPERMINT (UNII: V95R5KMY2B)			
SORBITOL (UNII: 506T60A25R)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
<b>Product Characteristics</b>			
<b>Color</b>	white	<b>Score</b>	no score

<b>Shape</b>	ROUND	<b>Size</b>	13mm	
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	AP;019	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54738-518-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2011	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part332	03/01/2011		

**Labeler** - Richmond Pharmaceuticals, Inc. (043569607)

**Registrant** - Advance Pharmaceutical Inc. (078301063)

### Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-518)

Revised: 10/2017

Richmond Pharmaceuticals, Inc.