

## **ANTIFLATULENT - simethicone tablet, chewable**

### **Major Pharmaceuticals**

*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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### **Major Simethicone**

#### **ACTIVE INGREDIENT(in each tablet)**

Simethicone 80 mg

#### **PURPOSE**

Antigas

#### **USE(S)**

relieves:

- pressure
- bloating
- symptoms referred to as gas

#### **WARNINGS**

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#### **KEEP OUT OF REACH OF CHILDREN**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

#### **DIRECTIONS**

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime
- do not exceed 6 tablets per day unless directed by a physician

#### **OTHER INFORMATION**

- do not use if inner seal is broken
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

#### **INACTIVE INGREDIENTS**

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol.

## QUESTIONS

Call (800) 616-2471

## PRINCIPAL DISPLAY PANEL

NDC 0904-7206-60

MAJOR

**Simethicone 80 mg**

Antiflatulent

Relieves gas pain, pressure and bloating

100 Chewable Tablets

**MAJOR**<sup>®</sup>  
NDC 0904-7206-60  
  
**Simethicone**  
**80 mg**  
**Antiflatulent**  
  
Relieves gas pain,  
pressure and bloating  
  
**100 Chewable Tablets**

**Drug Facts**  

<b>Active ingredient (in each tablet)</b> Simethicone 80 mg	<b>Purpose</b> Antigas
<b>Uses</b> relieves: ■ pressure ■ bloating ■ symptoms referred to as gas	
<b>Warnings</b> Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.	
<b>Directions</b> ■ chew 2 to 4 tablets thoroughly as needed after meals and at bedtime ■ do not exceed 6 tablets per day unless directed by a physician	
<b>Other information</b> ■ do not use if inner seal is broken ■ store at room temperature ■ avoid high humidity and excessive heat, above 40°C (104°F)	
<b>Inactive ingredients</b> compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol.	
<b>Questions or comments?</b> Call (800) 616-2471	

  
Distributed by:  
**MAJOR<sup>®</sup> PHARMACEUTICALS**  
Livonia, MI 48152  
Rev. 09/21 M-30 Re-order No. 701298

LOT:  
EXP:

## ANTIFLATULENT

simethicone tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7206
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	
SUGARCANE (UNII: 81H2R5AOH3)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	PEPPERMINT	Imprint Code	G;103	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7206-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332		10/04/2021	

**Labeler -** Major Pharmaceuticals (191427277)

## Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(0904-7206)

Revised: 1/2022

Major Pharmaceuticals