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.

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

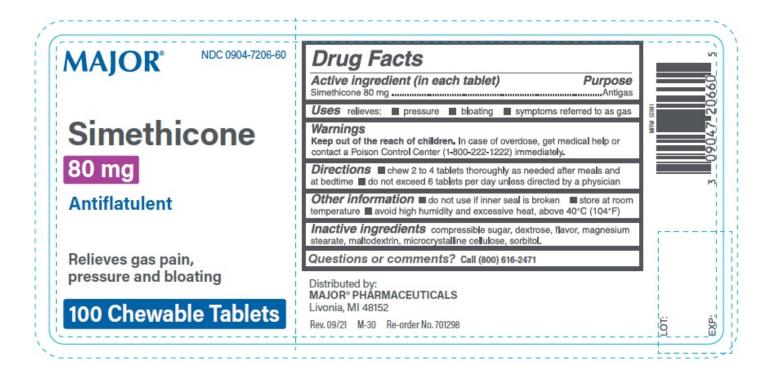
PRINCIPAL DISPLAY PANEL

NDC 0904-7206-60 MAJOR **Simethicone 80 mg**

Antiflatulent

Relieves gas pain, pressure and bloating

100 Chewable Tablets



ANTIFLATULENT simethicone tablet, chewable Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	80 mg

Inactive Ingredients				
Ingredient Name	Strength			
SUGARCANE (UNII: 81H2R5AOH3)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
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