

SIMETHICONE- simethicone tablet, chewable
ATLANTIC BIOLOGICALS CORP.

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.

gc 791

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Anti-Gas

Uses

relieves pressure, bloating, and fullness
commonly referred to as gas

Warnings

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children.

Directions

- chew or crush tablet completely before swallowing
- adults and children 12 years and over: take 1-2 tablets as needed after meals and at bedtime.

Do not exceed 6 tablets in 24 hours except under the advice and supervision of a doctor.

- children under 12 years: ask a doctor

Other information

- each tablet contains: **calcium 65 mg**
- Tamper Evident: Do not use if imprinted seal under cap is missing or broken
- store at room temperature, 15°C - 30°C (59°F - 86°F)
- protect from moisture

Inactive ingredients

cellulose, corn starch, crospovidone, dextrates hydrated, flavor, magnesium stearate, silica, sucralose, calcium phosphate.

Questions or comments?

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

package Label

17856-0791-01
GAS RELIEF (SIMETHICONE) 
80 MG TAB
MINT FLAVOUR

See package insert for indications and dosage schedule

Store at room temperature 15°C - 30°C (59°F - 86°F) Protect from moisture.
 ** Keep this and all medication out of the reach of children**



17856-0791-01 **Dosage 80 MG TABLETS**
GAS RELIEF **Qty: 50 TABLETS**
(SIMETHICONE)



GTIN: 00117856079118
S/N: 01653801
Exp: 07/17/22
Lot: 016538



Packaged by: Unit Dose Solutions
 Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,
 Miami FL 33179

Rev.08/21 **Call to Reorder: 800.509.7592**

SIMETHICONE

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0791(NDC:57896-791)
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	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
DEXTRATES (UNII: G263MI44RU)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)				
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPVIDONE (UNII: 2S7830E561)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	PEPPERMINT	Imprint Code	44;137	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0791-1	50 in 1 BOX	04/11/2022	
1	NDC:17856-0791-2	1 in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part332	02/10/2022		

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Registrant - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-0791)