

FIRSTCARE MAXIMUM STRENGTH GAS RELIEF SIMETHICONE 250 MG ANTI-GAS- simethicone tablet, chewable
USpharma Ltd

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.

FIRSTCARE MAXIMUM STRENGTH GAS RELIEF SIMETHICONE 250 mg Anti-gas

DRUG FACTS

Active ingredient (in each chewable)

Simethicone, 250 mg

Purpose

Antigas

Uses

for the relief of

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

Keep out of reach of children.

In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Directions

- adults and children 12 years and older: take 1 or 2 chewables as needed after meals and at bedtime.
- do not exceed 2 chewables in 24 hours except under the advice and supervision of a physician.

Other information

- each chewable contains **sodium 5 mg.** very low sodium
- store at controlled room temperature 20-25°C (68-77°F).
- protect from light, heat and moisture.
- **Child Resistant Container; do not use if printed seal under cap is broken or missing.**

Inactive ingredients:

carnauba wax, citric acid, croscarmellose sodium, crospovidone, FD&C red #40, flavors, glucose syrup, glycerin, gum arabic, maltitol solution, mannitol, powdered milk, propylene glycol, sorbitol, starch, sucralose, sucrose.

Questions or comments?

Call **1-800-227-6151**

USpharma

13900 NW 57th Court, Miami Lakes, FL 33014

1-800-227-6151 www.uspharmaltd.com

Principal display Panel-250 mg bottle label

FIRSTCARE

MADE IN USA

NDC 71594-707-08

MAXIMUM STRENGTH

GAS RELIEF

SIMETHICONE 250 mg

Anti-gas

Fast Relief of:

**Bloating, Pressure,
Gas discomfort**

Mixed Berry Flavor

20 SOFT CHEWABLES



FIRSTCARE MAXIMUM STRENGTH GAS RELIEF SIMETHICONE 250 MG ANTI-GAS

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71594-707
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	250 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPROVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CORN SYRUP (UNII: 9G5L16BK6N)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACACIA (UNII: 5C5403N26O)	
MALTITOL (UNII: D65DG142WK)	
MANNITOL (UNII: 3OWL53L36A)	
MILK PROTEIN CONCENTRATE (UNII: 871QYF3I7B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red	Score	no score
Shape	SQUARE	Size	15mm
Flavor	BERRY (MIXED BERRY)	Imprint Code	7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71594-707-08	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	07/04/2023	

Labeler - USpharma Ltd (080664601)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	manufacture(71594-707)

Revised: 5/2023

USpharma Ltd