## GAS RELIEF - simethicone tablet, chewable Strategic Sourcing Services LLC

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

#### Active ingredient (in each tablet)

simethicone 125 mg

#### **Purpose**

Anti-gas

#### Uses

relieves:

- pressure
- bloating
- symptoms referred to as gas

#### Warnings

**Keep out of the reach of children.** In case of overdose, get medical help or contact a poison control center immediately.

#### **Directions**

- chew 1 to 2 tablets thoroughly as needed after meals and at bedtime
- do not exceed 4 tablets in a 24 hour period except under the advice and supervision of a physician

#### Other information

- do not use if any individual blister unit is broken or open
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

#### Inactive ingredients

D&C red 30 aluminum lake, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol, sucrose

#### **Principal Display Panel**

sunmark

COMPARE TO GAS-X EXTRA STRENGTH ACTIVE INGREDIENT\*

NDC 49348-863-48

gas relief

Extra Strength

Relieves these gas symptoms:

Discomfort, pressure & bloating

ANTIGAS SIMETHICONE 125 mg

CHERRY CREME FLAVOR

18 CHEWABLE TABLETS



#### **GAS RELIEF**

simethicone tablet, chewable

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-863 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg	

Inactive Ingredients		
Ingredient Name	Strength	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)		
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ 35W2)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
SORBITOL (UNII: 506T60A25R)		
SUCROSE (UNII: C151H8M554)		

Product Characteristics					
Color	pink	Score	no score		
Shape	ROUND	Size	16mm		
Flavor	CHERRY	Imprint Code	G134		
Contains					

Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
NDC:49348-863-48	2 in 1 CARTON	09/18/2019					
1	9 in 1 BLISTER PACK; 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	10/01/2012			

### **Labeler -** Strategic Sourcing Services LLC (116956644)