

**PEDIACARE SIMETHICONE ANTIGAS- simethicone emulsion**  
**Strides Pharma Inc**

*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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**Pediacare Gas RELIEF DROPS**

**Drug Facts**

**Active ingredient**

*(in each 0.3 mL)*

Simethicone 20 mg

(provided as simethicone emulsion 66.7 mg)

**Purpose**

Antigas

**Uses**

relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

**Warnings**

**Keep out of reach of children.**

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

**Directions**

- **shake well before using**
- find right dose on chart below. If possible, use weight to determine dose; otherwise, use age.
- measure only with the enclosed syringe
- remove cap and insert syringe into the bottle. Fill syringe to recommended dosage level.
- dispense liquid slowly into child's mouth, toward inner cheek
- may be mixed with 1 oz. of cool water, infant formula or other suitable liquids
- all dosages may be repeated as needed, after meals and at bedtime or as directed by a physician
- do not exceed 12 doses per day
- clean syringe and replace cap tightly on bottle
- mL = millilitre

<b>Age(yrs)</b>	<b>weight(lbs)</b>	<b>dose</b>
infants under 2	under 24	0.3mL
children 2 and over	24 and over	0.6mL

**Other information**

- do not freeze
- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

carboxymethylcellulose sodium, citric acid, flavor, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate , sucralose, xanthan gum

**Questions**

**1-888-474-3099**

Monday – Friday 8 am to 5 pm

Eastern standard time.

**PediaCare.com**

**Principal Display Panel**

INFANTS 0-36 months

PediaCare®

Gas Relief DROPS

SIMETHICONE-ANTIGAS

DYE-FREE Berry Flavor

1 FL OZ (30 mL)



Carton

<ul style="list-style-type: none"> <li>do not exceed 12 doses per day</li> <li>clean syringe and replace cap tightly on bottle</li> <li>mL = milliliter</li> </ul> <table border="1"> <thead> <tr> <th>age (yrs)</th> <th>weight (lbs)</th> <th>dose</th> </tr> </thead> <tbody> <tr> <td>infants under 2</td> <td>under 24</td> <td>0.3 mL</td> </tr> <tr> <td>children 2 and over</td> <td>24 and over</td> <td>0.6 mL</td> </tr> </tbody> </table> <p><b>Other information</b> ■ Tamper-Evident: if foil seal under cap is broken or missing then do not use. ■ do not freeze ■ store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients</b> carboxymethylcellulose sodium, citric acid, flavor, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum</p> <p><b>Questions?</b> 1-888-474-3099 Monday-Friday 8am-5pm eastern standard time.</p> <p><b>PediaCare.com</b> Manufactured for Strides Pharma Inc. East Brunswick, NJ 08816 © 2017 Made in the USA. 011-5601L-R01</p>	age (yrs)	weight (lbs)	dose	infants under 2	under 24	0.3 mL	children 2 and over	24 and over	0.6 mL	<p><b>Infants</b> 0-36 months</p> <p>Fast Acting <b>PediaCare</b> 100% dedicated to kids™</p> <p><b>Gas RELIEF DROPS</b> <b>SIMETHICONE - ANTIGAS</b></p> <p>Safe enough to use at every feeding* <b>NON-STAINING</b> *Use as Directed</p> <p>Up to 100 DOSES 1 FL OZ (30 mL)</p>	<p><b>Active ingredient (in each 0.3 mL) Purpose</b> Simethicone 20 mg (provided as simethicone emulsion 66.7 mg).....Antigas</p> <p><b>Uses</b> relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods</p> <p><b>Warnings</b> Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.</p> <p><b>Directions</b> ■ shake well before using ■ find right dose on chart below. If possible, use weight to determine dose; otherwise, use age. ■ measure only with the enclosed syringe ■ remove cap and insert syringe into the bottle. Fill syringe to recommended dosage level. ■ dispense liquid slowly into child's mouth, toward inner cheek ■ may be mixed with 1 oz. of cool water, infant formula or other suitable liquids ■ all dosages may be repeated as needed, after meals and at bedtime or as directed by a physician</p>
age (yrs)	weight (lbs)	dose									
infants under 2	under 24	0.3 mL									
children 2 and over	24 and over	0.6 mL									

Label

simethicone emulsion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59556-853
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	0.011 g in 1 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.211 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-853-59	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	08/01/2011	

**Labeler** - Strides Pharma Inc (078868278)

### Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 9/2017

Strides Pharma Inc