

## **GAS RELIEF- simethicone suspension/ drops**

### **Rugby Laboratories**

*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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### **Rugby infant drops**

#### **Active ingredient (in each 0.3 mL)**

Simethicone 20 mg

#### **Purpose**

Antigas

#### **Use**

relieves the symptoms referred to as gas

#### **Warnings**

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

#### **Directions**

- shake well before using
- 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
- fill enclosed dropper to recommended dosage level and dispense liquid slowly into baby's mouth, toward inner cheek
- may be mixed with 1 oz of water, infant formula or other suitable liquid
- for best results, clean dropper after each use and replace original cap

<b>Age (years)</b>	<b>Weight (lbs)</b>	<b>Dose</b>
infants (under 2)	under 24	0.3 mL
children (over 2)	over 24	0.6 mL

#### **Other information**

- store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date
- **TAMPER-EVIDENT: Do not use if foil seal under cap is broken or missing**

#### **Inactive ingredients**

carboxymethylcellulose sodium, citric acid, flavor, maltitol, microcrystalline cellulose, purified water, sodium benzoate, sodium citrate, xanthan gum.

# Questions or comments?

1-800-645-2158

## package Label

compare to the active ingredient of MYLICON DROPS RUGBY

NDC 0536-2220-75

GAS RELIEF DROPS

Simethicone Oral Suspension USP

Suitable for Infant Use

Antigas

Relieves the Symptoms Referred to as Gas

dye free formula

1 FL OZ (30 mL)

**Save carton for complete Drug Facts**

**Drug Facts**

Active ingredient (in each 0.3 mL)	Purpose
Simethicone 20 mg	Antigas

**Use**  
relieves the symptoms referred to as gas

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

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- for best results, clean dropper after each use and replace original cap

Age (years)	Weight (lbs)	Dose
infants (under 2)	under 24	0.3 mL
children (2 and over)	24 and over	0.6 mL

**Other information**

- store at room temperature • do not freeze
- see bottom panel for lot number and expiration date
- TAMPER-EVIDENT:** Do not use if foil seal under the cap is broken or missing

**Drug Facts (continued)**

**Inactive ingredients**  
carboxymethylcellulose  
sodium, citric acid, flavor,  
maltitol, microcrystalline  
cellulose, purified water,  
sodium benzoate, sodium  
citrate, xanthan gum.

**Questions or comments?**  
1-800-645-2158

**Rugby**®  
NDC 0536-2220-75

**COMPARE TO ACTIVE INGREDIENT IN MYLICON® DROPS\***

**GAS RELIEF DROPS**  
Simethicone Oral Suspension USP

**Suitable for Infant Use**  
Antigas  
Relieves the Symptoms Referred to as Gas

**DYE-FREE FORMULA**

1 FL OZ (30 mL)

**DOSAGE**

Children 2 years and over — 0.6 mL

Infants under 2 years — 0.3 mL

PLASTIC DROPPER ENCLOSED

\*Rugby Laboratories is not affiliated with the owner of the trademark Mylicon®.

Distributed by:  
Rugby Laboratories  
17177 N Laurel Park Drive,  
Suite 233  
Livonia, MI 48152  
www.rugbylaboratories.com  
419-26119-3 Rev. 03/17  
R-99 Re-order No. 370083

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## GAS RELIEF

simethicone suspension/ drops

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-2220	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 0.3 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			
	ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
	MALTITOL (UNII: D65DG142WK)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	WATER (UNII: 059QF0KO0R)			
	SODIUM BENZOATE (UNII: OJ245FE5EU)			
	SODIUM CITRATE (UNII: 1Q73Q2JULR)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
<b>Product Characteristics</b>				
<b>Color</b>	white (off-white)	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0536-2220-75	1 in 1 CARTON	03/01/2017	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part332	12/01/2010		

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - GCP Laboratories (965480861)

**Establishment**

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(0536-2220)

Revised: 12/2019

Rugby Laboratories