

**INFANTS- simethicone suspension/ drops**  
**RUGBY LABORATORIES**

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**Rugby® Infants' Gas Relief Simethicone Drops**

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

Simethicone 20 mg

**Purpose**

Antigas

**Uses**

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

**Warnings**

**Keep out of reach of children.**

**Overdose warning: In case of overdose get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick medical attention is critical even if you do not notice any signs or symptoms.**

**Directions**

- **shake well before using**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- only use the enclosed syringe. **Do not use other syringe, dropper, spoon or dosing device when giving this medicine to your child.**
- remove cap and insert syringe into the bottle.
- pull syringe up until filled to the prescribed level, simply push syringe back until you have reached the described level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
- 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.
- dosage can also be mixed with 1 oz. cool water, infant formula or other suitable liquids.
- Replace cap tightly to maintain child resistance
- mL = milliliter

Age (yr)	Weight (lb)	Dose (mL)
infants under 2	under 24	0.3

children over 2	over 24	0.6
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## Other information

- **tamper evident: do not use if printed seal under cap is broken or missing**
- Store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date

## Inactive ingredients

carboxymethylcellulose sodium, citric acid, flavors, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum

## Questions or comments?

1-800-645-2158

## Principal Display Panel

**Rugby®**

Compare to the active ingredient in Infants' Mylicon® Drops\*

**NDC 0536-1303-75**

Infants'

**Simethicone Drops**

Antigas

- Dye-free
- Non-staining formula
- No Saccharin
- No Artificial Color
- No Artificial Flavor

1 FL OZ (30 mL) 100 DOSES

Distributed by:

**RUGBY LABORATORIES**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

[www.rugbylaboratories.com](http://www.rugbylaboratories.com)

Syringe Enclosed. This bottle contains 100 doses (0.3 mL/dose)

\*This product is not manufactured or distributed by Infirst Healthcare Inc., the distributor of Infants' MYLICON® Drops.



## INFANTS

simethicone suspension/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1303
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE, UNSPECIFIED	20 mg in 0.3 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1303-75	1 in 1 CARTON	09/01/2020	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	09/01/2020	

**Labeler** - RUGBY LABORATORIES (079246066)