# INFANTS GAS RELIEF- simethicone suspension Family Dollar (FAMILY WELLNESS)

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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#### **Drug Facts**

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

Simethicone 20 mg

#### **Purpose**

**Antigas** 

#### Uses

relieves the discomfort of infant gas frequently caused by ar 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 (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

#### **Directions**

- shake well before using
- mL=milliliter
- measure only with enclosed syringe provided. Do not use any other dosing device
- keep dosing device with product
- replace cap tightly to maintain child resistance
- remove cap and insert syringe into hole at top of the bottle and turn upside down
- pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back until have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek)
- dosage can also be mixed with 1 oz, cool water, infant formula, or other suitable liquids
- clean syringe well after use
- 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
- find the right dose on chart below. If possible, use weight to dose; otherwise, use

Weight (lb)	Age (yr)	Dose (mL)
under 24 lbs	under 2 years	0.3 mL
over 24 lbs	over 2 years	0.6 mL

#### Other information

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

#### **Inactive ingredients**

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

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT IN MYLICON® GAS RELIEF\*

Infants Gas Relief

Simethicone 20 mg - antigas

- Gently breaks down baby's gas bubbles
- Safe enough to use at every feeding\*\*

Dye-Free

Alcohol-Free

Non-staining

Saccharin free

FL OZ (mL)

Dosing syringe

Use only with enclosed syringe

\*\*use as directed

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND THE BOTTLE IS BROKEN OR MISSING

\*This product is not manufactured or distributed by McNeil Consumer Healthcrae, distributor of Mylicon® Gas Relief

**DISTRIBUTED BY:** 

MIDWOOD BRANDS, LLC 10611 MONROE RD., MATTHEWS, NC 28105

#### Package Label



simethicone suspension

**INFANTS GAS RELIEF** 

simethicone suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-325
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	<b>Basis of Strength</b>	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	20 mg in 0.3 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
MALTITOL (UNII: D65DG142WK)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
XANTHAN GUM (UNII: TTV12P4NEE)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-325- 01	1 in 1 BOX	02/28/2017	04/26/2024
1		30 mL in 1 BOTTLE; 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	02/28/2017	04/26/2024

## Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021 Family Dollar (FAMILY WELLNESS)