INFANT GAS RELIEF DYE FREE- simethicone suspension AmerisourceBergen (Good Neighbor Pharmacy) 46122

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.

Drug Facts

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddenings
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Liver warning: This product contains acetamnophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Keep out of reach of children.

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

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

Other information

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

Inactive ingredients

citric acid, carboxymethylcellulose sodium, flavors, 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 Mylicon® Gas Relief active ingredient*

Infant Gas Relief

Simethicone 20mg - Antigas

Dve-Free

- Alcohol Free
- Saccharin Free
- Non-Staining

FL OZ (mL)

Use only with enclosed syringe

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 AmerisourceBergen

1300 Morris Drive

Chesterbrook, PA 19087

Visit us at www.mygnp.com

Package Label



Other information

do not freeze

citrate, xanthan gum

Mylicon® Gas Relief.



GOOD NEIGHBOR PHARMACY Infant Gas Relief

INFANT GAS RELIEF DYE FREE

simethicone suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-051
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICO NE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 0.3 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		

MALTITOL (UNII: D65DG142WK)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:46122-051- 03	1 in 1 BOX	06/30/2014	12/31/2022
1	30 mL in 1 BOTTLE, PLASTIC; 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	06/30/2014	12/31/2022

Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

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