INFANTS GAS RELIEF- simethicone suspension Geri-Care Pharmaceuticals, Corp

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.

hst infants gas relief

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 the inner cheek dosage can also be mixed with 1 oz. of cool water, infant formula or other suitable liquids
- clean dropper well after each use and replace original cap on bottle

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

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

Inactive ingredients

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

Questions or comments?

1-800-540-3765

Package Label

NDC 57896-798-01

Health star

the sensible choice for price and health

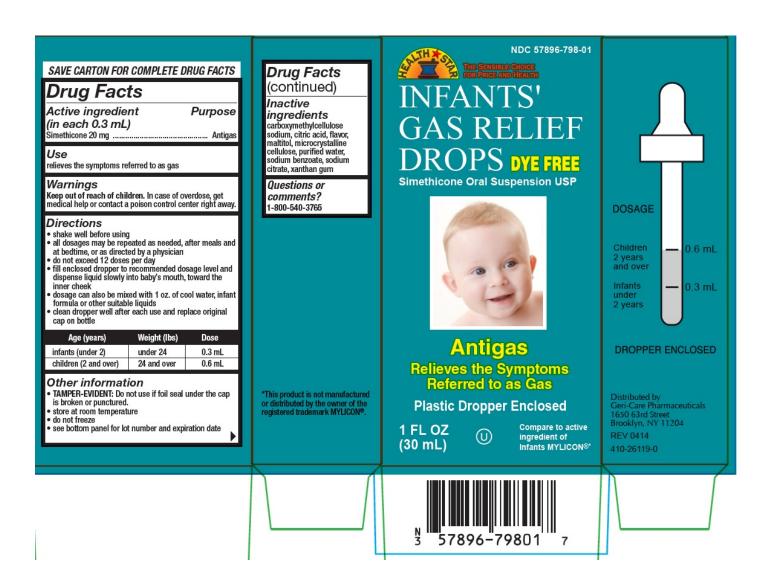
INFANTS' GAS RELIEF DROPS

dye free

Simethicone Oral Suspension USP

Antigas Relieves the Symptoms Referred to as Gas

Plastic Dropper Enclosed
Antigas
Relieves the Symptoms
Referred to as Gas
Simethicone Oral Suspension USP
1 FL OZ
(30 mL)
Compare to active
ingredient of
Infants MYLICON®*



INFANTS GAS RELIEF

simethicone suspension

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:57896-798 Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DIMETHICO NE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) DIMETHICONE 20 mg in 0.3 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
MALTITOL (UNII: D65DG142WK)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
WATER (UNII: 059QF0KO0R)		

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:57896-798-01	1 in 1 BOX	05/01/2014	
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	05/01/2014	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - GCP Laboratories (965480861)

Establishment			
Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(57896-798)

Revised: 12/2019 Geri-Care Pharmaceuticals, Corp