

SIMETHICONE INFANT GAS RELIEF DROPS- simethicone suspension
AARNA USA Inc.

SIMETHICONE INFANT GAS RELIEF DROPS
fast instant gas relief

Active ingredient (in each 0.3 mL)

Simethicone 20 mg

Purpose

Antigas

Uses

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

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 printed seal under 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 strawberry, Microcrystalline cellulose, Polysorbate 60, Potassium sorbate, Purified water, Sodium benzoate, Sorbitan monostearate, Sorbitol solution, Xanthan gum.

Questions or comments ?

Call toll-free 1-877-225-6999.

Manufactured for:

AARNA USA Inc.

Leland, NC-28451

NDC 82568-0017-3

Infant's Gas Relief

Simethicone

Drops oral suspension USP

No Artificial Flavors
Gently works in minutes
Relieves stomach discomfort from gas

Dye free
Gluten free
Paraben free
alcohol free

Safe for Newborns 1 fl oz (30mL)

Drug Facts

Active ingredient (in each 0.3 mL)
Simethicone 20 mg 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 syringe 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 syringe well after each use and replace original cap on bottle

KT154-2501-00

KTG/25/666/2017

Aarna USA
Manufactured for:
AARNA USA Inc.
Leland, NC-28451

PEEL HERE FOR MORE DRUG FACTS

Exclusively distributed by: **Akron Pharma Inc.**, Fairfield, NJ-07004

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 20° - 25°C (68° - 77°)
- do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredients Carboxymethylcellulose sodium, Citric acid, Flavor strawberry, Microcrystalline cellulose, Polysorbate 60, Potassium sorbate, Purified water, Sodium benzoate, Sorbitan monostearate, Sorbitol solution, Xanthan gum.

Questions or comments ? Call toll-free 1-877-225-6999.



SAVE CARTON FOR COMPLETE DRUG FACTS

Drug Facts

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

Purpose
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
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• store at room temperature 20°-25°C (68°-77°F)
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• see bottom panel for lot number and expiration date

Exclusively distributed by: Akron Pharma Inc., Fairfield, NJ-07004

Drug Facts (continued)

Inactive ingredients
carboxymethylcellulose sodium, citric acid, flavor strawberry, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol solution, xanthan gum

Questions or comments?
Call toll-free 1-877-225-6999.

*This product is not manufactured or distributed by the owner of the registered trademark MYLICON®.

Aarna USA
Manufactured for:
AARNA USA Inc.
Leland, NC-28451

KTK/25/666/2017



K16A-C2501-00

NDC 82568-0017-3



Infant's Gas Relief

Simethicone

Drops oral suspension USP

No Artificial Flavors

Gently works in minutes

Relieves stomach discomfort from gas

Dye free
Gluten free
Paraben free
alcohol free

Safe for Newborns 1 fl oz (30mL)



Wash with cold water before use

NEW EASY DOSE SYRINGE ENCLOSED



NDC 82568-0017-4

Infant's Gas Relief

Simethicone

Drops oral suspension USP

No Artificial Flavors
Gently works in minutes
Relieves stomach discomfort from gas

Dye free
Gluten free
Paraben free
alcohol free

Safe for Newborns 4FL.OZ (118 mL)

Drug Facts

Purpose
Antigas

Active ingredient (in each 0.3 mL)
Simethicone 20 mg 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
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• store at room temperature 20°-25°C (68°-77°F)
• do not freeze
• see bottom panel for lot number and expiration date

Inactive ingredients Carboxymethylcellulose sodium, Citric acid, Flavor strawberry, Microcrystalline cellulose, Polysorbate 60, Potassium sorbate, Purified water, Sodium benzoate, Sorbitan monostearate, Sorbitol solution, Xanthan gum.

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K16B-L2501-01 KTK/25/666/2017

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SIMETHICONE INFANT GAS RELIEF DROPS

simethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82568-0017
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 0.3 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82568-0017-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2025	
2	NDC:82568-0017-3	1 in 1 PACKAGE	02/20/2025	
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M002	02/20/2025	

Labeler - AARNA USA Inc. (118515992)

Establishment

Name	Address	ID/FEI	Business Operations
KJD PHARMA PRIVATE LIMITED		877256314	manufacture(82568-0017)

Revised: 7/2025

AARNA USA Inc.