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, alter 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 82568-0017-4 | | pose | uyas | qlər | time, | se la | | | ua | Citric e 60, | | ٦ | 74 |
|---|---------|---------------------------------------|---|--|--|---|--------------|--|---|--|------------------------|----------------------------|---|
| Infant's Gas Relief | | Purpose | | get medical help | nd at bed | d dispens k int formu | Dose | 0.3 mL 0.6 mL | p is brok | ate se sodium, Cit Polysorbate 6 te, Sorbitan | 1-877-225-6999 | | 568 001 |
| Simethicone | | | | | ieals ar | evel and r cheek ter, infa | | | the ca | ose so e, Polys ate, Sc | 1-877- | | 3 82 |
| Drops oral suspension USP | | | | of overdose, away. | after m | sage le 1e inne ool wa | bs) | /er | Innder | ylcellul ellulose benzo | co | | |
| ANTIGAS *No artificial flavors or dyes. Gluten, Paraben and alcohol free Gently works in minutes | | | to as das | In case of ove tter right away. | as needed, after meals and at bedtime, | day mmended dosage level and dispense uth, toward the inner cheek rith 1 oz. of cool water, infant formula | Weight (Ibs) | under 24 24 and over | se if foil sea | AT INTIDET AND EXPIRATION DATE ITS Carboxymethylcellulose Microcrystalline cellulose, Pc fied water, Sodium benzoate, solution, Xanthan gum. | ts? Call toll-free | | |
| Relieves stomach discomfort from gas compare to active Ingredient of Infants MYLICON | Facts | edient 3 mL) | mp. referred | ch of children. | e using be repeated v a physiciar | s per s mo | ears) | infants (under 2) children (2 and over) | ther information AMPER-EVIDENT: Do not use if foil seal under the cap is broken or punctured. store at room temperature do not freeze | International of the second se | or commen | Use Only | |
| Safe for Newborns | Drug Fa | Active ingredient (in each 0.3 mL) | USe Use star somntoms referred to as ras | Warnings Keep out of reach of children. In case or contact a poison control center right | Directions • shake well befor • all dosages may or as directed by | not excee enclosed uid slowly sage can other suit | Age (years) | infants (under 2) children (2 and o | Other information • TAMPER-EVIDENT: Do or punctured. • store at room temperat • do not freeze | see boutonin pairei Inactive ingre acid, Flavor strawb Potassium sorbate monostearate, Sori | Questions or comments? | For Institutional Use Only | Adring USA Manufactured for: AARNA USA Inc. Leland, NC-28451 |
| 4FL.OZ (118 mL) | | | | <u>>x∘</u> | | ••• | | | 3 | - Let L | 9 | ш. | Adr Manufac AARNA |

SIMETHICONE INFANT GAS RELIEF DROPS

simethicone suspension **Product Information Product Type** HUMAN OTC DRUG NDC:82568-0017 Item Code (Source) **Route of Administration** ORAL **Active Ingredient/Active Moiety** Ingredient Name Basis of Strength Strength **DIMETHICONE** (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) DIMETHICONE 20 mg in 0.3 mL **Inactive Ingredients Ingredient Name** Strength CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311) ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

| | ICROCRYSTALLI | NE CELLU | LOSE (UNII: OP1R32D61U) | | | | |
|-------------|---|--------------------------|--|------|---------------------------------------|------------------|-------------|
| РС | DLYSORBATE 60 | (UNII: CAL | 22UVI4M) | | | | |
| РС | DTASSIUM SORB | ATE (UNII: | 1VPU26JZZ4) | | | | |
| W | ATER (UNII: 059Q | F0KO0R) | | | | | |
| sc | DDIUM BENZOAT | re (unii: oj | 245FE5EU) | | | | |
| sc | ORBITAN MONOS | STEARATE | (UNII: NVZ4I0H58X) | | | | |
| sc | DRBITOL (UNII: 50 | 06T60A25R |) | | | | |
| XA | NTHAN GUM (UN | NII: TTV12P | 4NEE) | | | | |
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| Pı | roduct Chara | acterist | ics | | | | |
| Co | olor | | | Sco | ore | | |
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| Pa | ackaging | | | | | | |
| Pa # | ackaging Item Code | | Package Description | | Marketing Start Date | Marketin Date | |
| # | | 118 mL in Product | Package Description 1 BOTTLE; Type 0: Not a Combination | on (| | | |
| # | Item Code | | | on (| Date | | |
| # | Item Code | | | on (| Date | | |
| # | Item Code | Product | 1 BOTTLE; Type 0: Not a Combinatio | on (| Date | | |
| # | Item Code NDC:82568- 0017-4 | Product | 1 BOTTLE; Type 0: Not a Combinatio | | Date | | e ng End |
| # 1 M | Item Code NDC:82568- 0017-4 Iarketing Marketing | Product Inform App | 1 BOTTLE; Type 0: Not a Combination Nation lication Number or Monograp | | Date 02/20/2025 Marketing Start | Dato | e ng End |

Labeler - AARNA USA Inc. (118515992)

Revised: 3/2025

AARNA USA Inc.