INFANT GAS RELIEF- simethicone suspension/ drops AMERISOURCEBERGEN DRUG CORPORATION

GNP infant drops

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 inner cheek
- dosage can also be mixed with 1 oz. of cool water, infan 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 (over 2) | 24 and over | 0.6 mL |

Other information

- 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



INFANT GAS RELIEF

simethicone suspension/ drops

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46122-547 |
|-------------------------|----------------|--------------------|---------------|
| 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 (UNII: K6790BS311) | | | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | | |
| MALTITOL (UNII: D65DG142WK) | | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |

| Product Characteristics | | | | |
|-------------------------|--------|--------------|--|--|
| Color | white | Score | | |
| Shape | | Size | | |
| Flavor | CHERRY | Imprint Code | | |
| Contains | | | | |

| Packaging | | | | |
|----------------------|---|------------|-----------------------|--|
| # Item Code | Item Code Package Description | | Marketing End Date | |
| NDC:46122- 547-03 | 1 in 1 CARTON | 11/16/2018 | | |
| 1 | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M002 | 06/01/2018 | |
| | | | |

Labeler - AMERISOURCEBERGEN DRUG CORPORATION (007914906)

Registrant - GCP Laboratories (965480861)

| Establishment | | | | |
|------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| GCP Laboratories | | 965480861 | manufacture(46122-547) | |

Revised: 7/2023

AMERISOURCEBERGEN DRUG CORPORATION