# INFANTS NON-STAINING GAS RELIEF - simethicone solution/ drops H E B

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**HEB Infants Gas Relief Drops** 

## **ACTIVE INGREDIENT (in each 0.3 mL)**

Simethicone 20 mg

#### **PURPOSE**

**Antigas** 

### USE(S)

relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

#### WARNINGS

When using this product do not exceed 12 doses per day

#### **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.
- fill enclosed dropper to recommended dosage level
- dispense liquid slowly into baby's mouth, toward the inner cheek
- may mix with 1 oz. of cool water, infant formula or other suitable liquids.
- clean dropper after each use and close the bottle to maintain child resistance

| age (yr)        | weight (lb) | dose   |
|-----------------|-------------|--------|
| infants under 2 | under 24    | 0.3 mL |
| children over 2 | over 24     | 0.6 mL |

#### OTHER INFORMATION

store at room temperature

#### **INACTIVE INGREDIENT SECTION**

benzoic acid, flavor, magnesium aluminum silicate, purified water, simethicone emulsion, sorbitol, xanthan gum.

#### **QUESTIONS?**

You may report serious side effects to 1-609-860-2600 (Monday-Friday 8 am-4 pm EST).

#### PRINCIPAL DISPLAY PANEL

Compare to Infants' Mylicon® Drops Non-Staining active ingredient\* NDC 37808-014-09

**HEB** 

Infants' Non-Staining

#### **Gas Relief**

## **Drops**

simethicone 20 mg

#### **Anti-Gas**

- Fast Relief of Gas Symptoms
- No Artificial flavor
- Gentle & Safe\*\*
- Alcohol Free
- Dye free

## 1 FL OZ (30 mL)

<sup>\*\*</sup>Use only as directed, do not exceed more than 12 doses per day.



## **INFANTS NON-STAINING GAS RELIEF**

simethicone solution/ drops

| Product Information     |                |                    |               |  |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-014 |  |
| Route of Administration | ORAL           |                    |               |  |

| Active Ingredient/Active Moiety                                |                          |                 |  |
|--|--------------------------|-----------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength        |  |
| DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) | DIMETHICONE              | 20 mg in 0.3 mL |  |

| Inactive Ingredients                           |          |  |
|--|----------|--|
| Ingredient Name                                | Strength |  |
| BENZOIC ACID (UNII: 85KN0B0MIM)                |          |  |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) |          |  |
| WATER (UNII: 059QF0KO0R)                       |          |  |

SORBITOL (UNII: 506T60A25R)

XANTHAN GUM (UNII: TTV12P4NEE)

| Product Characteristics |                   |              |  |  |
|-------------------------|-------------------|--------------|--|--|
| Color                   | WHITE (off-white) | Score        |  |  |
| Shape                   |                   | Size         |  |  |
| Flavor                  |                   | Imprint Code |  |  |
| Contains                |                   |              |  |  |

| P | Packaging            |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:37808-<br>014-09 | 1 in 1 CARTON   | 11/15/2021              |                       |
| 1 |                      | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | part332                                     | 11/15/2021              |                       |
|                       |   |                         |                       |

## **Labeler -** H E B (007924756)

| Establishment         |         |           |                            |  |
|-----------------------|---------|-----------|----------------------------|--|
| Name                  | Address | ID/FEI    | <b>Business Operations</b> |  |
| Guardian Drug Company |         | 119210276 | MANUFACTURE(37808-014)     |  |

Revised: 12/2023 H E B