

INFANTS GAS RELIEF - simethicone solution/ drops
Supervalu Inc.

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.

Equaline Infant's 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

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WHEN USING THIS PRODUCT

do not exceed 12 doses per day

KEEP OUT OF THE 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
- 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 INGREDIENTS

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

PRINCIPAL DISPLAY PANEL

Compare to Mylicon[®] infant drops active ingredient*

NDC 41163-096-09

EQUALINE

infants'

gas relief

drops

simethicone 20 mg

(anti-gas)

- gently breaks down baby's gas bubbles
- safe enough to use at every feeding**

DYE-FREE

NON-STAINING

**USE AS DIRECTED

1 FL OZ (30 mL)



INFANTS GAS RELIEF

simethicone solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-096
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
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BENZOIC ACID (UNII: 8SKN0B0MIM)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-096-09	1 in 1 CARTON	08/26/2021	
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 FINAL	part332	08/26/2021	

Labeler - Supervalu Inc. (006961411)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(41163-096)

Revised: 5/2021

Supervalu Inc.