MOMMYS BLISS GAS RELIEF SIMETHICONE DROPS- dimethicone solution/drops

MOM Enterprises, 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.

Mommy's Bliss Gas Relief Simethicone Drops

Drug Facts

Active ingredient (in each 0.3 mL)

Simethicone 20 mg

Purpose

Antigas

Uses

Relieves the discomfort of infant gas frequently caused by air swallowing or certain formulas or foods

Warnings

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick medical attention is critical even if you do not notice any sign or symptoms.

Directions

- shake well before using
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- 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, cool water, infant formula or other suitable liquids
- clean dropper well after each use
- mL = milliliter

Age (yr)	Weight (lb)	Dose (mL)	
infants under 2	under 24	0.3	
children over 2	over 24	0.6	

Other information

- tamper evident: do not use if printed seal under cap is broken or missing
- store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredinets

carboxymethylcellulose sodium, citric acid, ginger extract, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, stevia extract, xanthan gum.

Questions?

Call 1-877-457-4955

Package Labeling:



MOMMYS BLISS GAS RELIEF SIMETHICONE DROPS

dimethicone solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71444-789
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 majicalents	
Inactive Ingredients	

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
GINGER (UNII: C5529G5JPQ)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYSORBATE 60 (UNII: CAL22UVI4M)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0KO0R)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SORBITAN MONOSTEARATE (UNII: NVZ 4I0H58X)
SORBITOL (UNII: 506T60A25R)
XANTHAN GUM (UNII: TTV12P4NEE)

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71444- 789-01	1 in 1 BOX	01/05/2020		
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	01/05/2020	

Labeler - MOM Enterprises, Inc (135903776)

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