TEENY TUMMY GAS RELIEF DROPS- simethicone suspension
Akron Pharma

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.

TEENY TUMMY
fast instant gas relief
INFANT'S GAS RELIEF DROPS

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, 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. of cool water, infant 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	over 24	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 ?

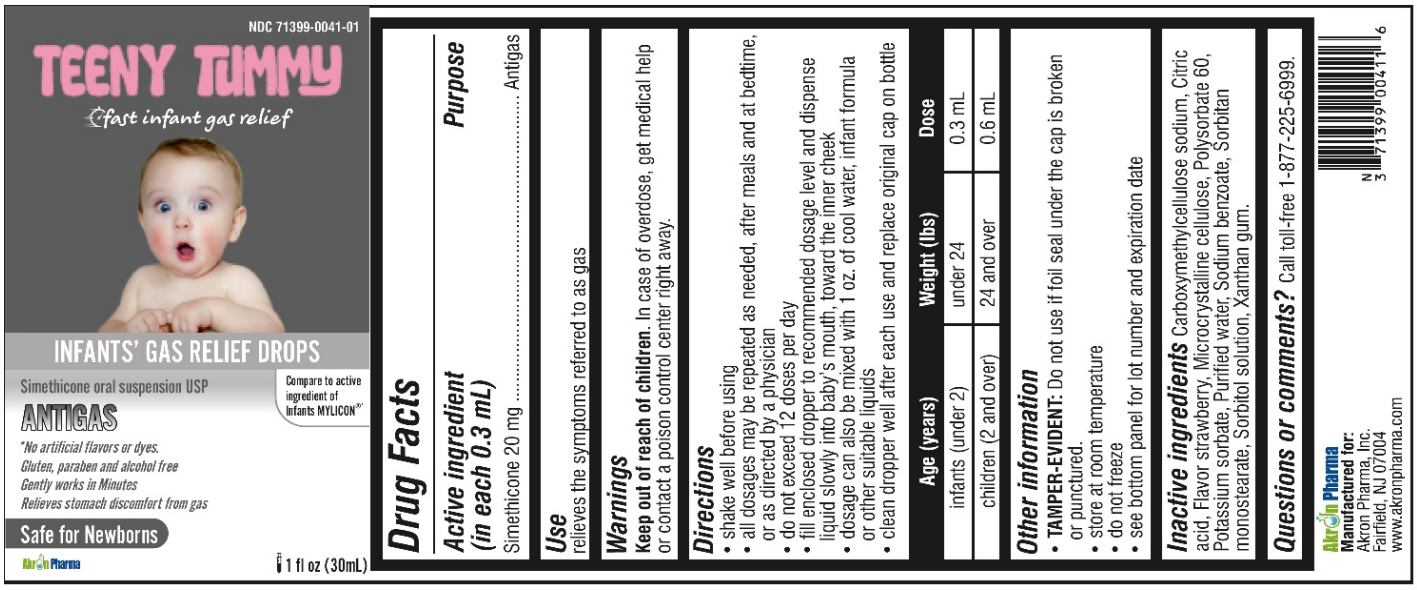
Call toll-free 1-877-225-6999.

Manufactured for:

Akron Pharma, Inc.

Fairfield, NJ 07004

www.akronpharma.com



TEENY TUMMY GAS RELIEF DROPS

simethicone suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-0041
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
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0041-1	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	08/04/2023	

Labeler - Akron Pharma (067878881)

Revised: 8/2023 Akron Pharma