

LITTLE FEVERS INFANT BERRY FEVER/PAIN RELIEVER- acetaminophen liquid
Medtech Products 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.

Little Fevers Infant Berry Fever Pain Reliever

Drug Facts

Active ingredient

(in each 5.0 mL)

Acetaminophen 160mg

Purpose

Pain Reliever/Fever Reducer

Uses

Temporarily:

- reduces fever
- relieves minor aches and pains which may be associated with the common cold, flu, headache, sore throat or toothache.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen.

Ask a doctor before use

if your child has liver disease.

Ask a doctor or pharmacist before use

if your child is taking the blood thinning drug warfarin.

Do not use:

- with any other products containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- If your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Sore Throat Warning: If sore throat is severe, persists for more than 2 days, or is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

When using this product

DO NOT EXCEED RECOMMENDED DOSAGE; taking more than the recommended dose (overdose) may not provide more relief and may cause liver damage.

Stop use and ask a doctor if:

- new symptoms occur
- fever gets worse or lasts more than 3 days
- pain gets worse or lasts more than 5 days
- redness or swelling is present. These could be signs of a serious condition.

Keep out of reach of children.**Overdose**

Warning: Taking more than the recommended dose (overdose) can cause serious liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

This product does not contain directions or complete warnings for adult use.

- Shake well before using.
- Find the right dose on the chart below. (If possible, use weight to determine dose; otherwise, use age.)
- Only use the enclosed AccuSafe™ syringe.
- **Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.**
- Remove cap, attach syringe to flow restrictor and invert bottle.
- Pull back syringe until filled to prescribed level and slowly dispense the liquid into your child's mouth (toward the inner cheek).
- If needed, repeat dose every 4 hours while symptoms last.
- Do not give more than 5 times in any 24-hour period (see overdose warning).
- Replace cap tightly to maintain child resistance.

Weight (lbs)	Age (yrs)	Dose
Under 24	Under 2	Ask a doctor
24-35	2-3	5.0 mL
36-47	4-5	7.5 mL

Other information

- Store at 20-25° C (68-77° F)
- AccuSafe™ dosing device enclosed.
- **Tamper Evident:** Do not use if printed shrinkband on bottle is broken or missing. Check expiration date on bottle or box before using.

Inactive ingredients

Citric Acid, Glycerin, High Fructose Corn Syrup, Natural Flavors, Polyethylene Glycol, Propylene Glycol, Purified Water, Sodium Benzoate and Sucralose

Questions?

For further information you may contact us at: **1-800-7-LITTLE** Mon. – Fri. 8:00 a.m. to 8:00 p.m. EST, or visit us at **www.LittleRemedies.com**.

PRINCIPAL DISPLAY PANEL

MEDICATED FOR INFANTS

Little Fevers[®] by Little Remedies[®]

NEW! AccuSafe[™] System

INFANT FEVER/PAIN RELIEVER

Acetaminophen

DYE-FREE

NO ARTIFICIAL FLAVORS

NO ALCOHOL, SACCHARIN OR DYES

GLUTEN FREE!

Natural BERRY Flavor

SEE NEW DOSING INFORMATION.

2 FL. OZ. (59 mL)



LITTLE FEVERS INFANT BERRY FEVER/PAIN RELIEVER

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-622
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
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Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-622-01	1 in 1 BOX		
1		1 in 1 BOX		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/01/2011	

Labeler - Medtech Products Inc. (122715688)

Revised: 7/2011

Medtech Products Inc.