

LITTLE FEVERS BY LITTLE REMEDIES- 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 Little Remedies

Drug Facts

Active Ingredient

(in each 1.0 mL)

Acetaminophen 80mg

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 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 right away

(1-800-222-1222). 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 dose; otherwise, use age.)
- Only use the enclosed dropper. Do not use any other dropper, spoon or dosing device when giving this medicine to your child.
- Fill the enclosed dropper to the prescribed level and slowly dispense the liquid into your child's mouth (towards 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 dropper tightly to maintain child resistance.

Weight (lbs)	Age (yrs)	Dose
Under 24	Under 2	Ask a doctor
24-35	2-3	2.0 mL (1.0 mL + 1.0mL)
36-47	4-5	3.0 mL (1.0mL + 1.0 mL + 1.0mL)

Other Information

- Store at 20-25°C (68-77°F)
- Oral dosing device enclosed.
- **Tamper Evident:** This product has a foil seal under the cap. Do not use if broken or missing.
- Check expiration date on bottle or box before using.

Inactive Ingredients:

Citric Acid, Glycerin, High Fructose Corn Syrup, Natural Flavors, PEG, 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.

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LR089101

PRINCIPAL DISPLAY PANEL

MEDICATED FOR INFANTS

Little Fevers®

by Little Remedies®

NEW!

FEVER/PAIN

RELIEVER

Acetaminophen

SAFE, GENTLE & EFFECTIVE

NATURAL BERRY FLAVOR

SEE NEW WARNINGS INFORMATION.

1 FL. OZ. (30 mL)

Little Fevers® Fever/Pain Reliever

Drug Facts
Active Ingredient (in each 1.0 mL) **Purpose**
Acetaminophen 80 mg...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 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 right away (1-800-222-1222). Prompt medical attention is critical even if you do not notice any signs or symptoms.

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Drug Facts (continued)

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Inactive Ingredients: Citric Acid, Glycerin, High Fructose Corn Syrup, Natural Flavors, PEG, Propylene Glycol, Purified Water, Sodium Benzoate and Sacralose

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.

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MEDICATED FOR INFANTS

LITTLE FEVERS®
 by Little Remedies®

NEW!

FEVER/PAIN RELIEVER
Acetaminophen

SAFE, GENTLE & EFFECTIVE

✓ **Fever Reducer**
 ✓ **Pain Reliever**

No ALCOHOL, SACCHARIN, DYES GLUTEN FREE!
GREAT TASTING NATURAL BERRY FLAVOR.

SEE NEW WARNINGS INFORMATION.
1 FL. OZ. (30 mL)

LITTLE FEVERS®
 by Little Remedies®

FEVER/PAIN RELIEVER

Little Remedies® Products provide safe and effective formulas to support the health and well-being of your child. When it comes to children's healthcare, we steadfastly believe "less is more" and strive to make sure that each of our products contains just what is needed for fast, safe, and effective relief - nothing more!

Little Remedies® Products avoid the use of unnecessary additives. Little Remedies® products contain:

- ✓ No Aspirin or Ibuprofen
- ✓ No Saccharin or Alcohol
- ✓ No Artificial Flavors
- ✓ No Artificial Dyes

This Little Remedies® Product has been specially formulated to provide small concentrated doses for easier administration.

For accurate dosing, only use the enclosed dropper and follow all dosing instructions.

LITTLE FEVERS BY LITTLE REMEDIES

acetaminophen liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63029-601

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-601-01	1 in 1 BOX		
1		30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part341	07/05/2010	

Labeler - Medtech Products Inc. (122715688)

Revised: 7/2010

Medtech Products Inc.