

**LITTLE REMEDIES INFANT 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 REMEDIES INFANT FEVER PAIN RELIEVER - Berry

Drug Facts

Active ingredient

(in each 5 mL)

Acetaminophen 160 mg

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.

Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash.

If skin reaction occurs, stop use and seek medical help right away.

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.

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.

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.

When using this product do not exceed recommended dosage (see overdose warning.)

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**
- **do not give more than directed (see overdose warning)**
- **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
- remove cap, insert 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
- replace cap tightly to maintain child resistance

mL=mililiter

Weight (lbs)	Age (yrs)	Dose
Under 24	Under 2	Ask a doctor
24-35	2-3	5 mL

Other information

- each 5 mL contains: **sodium 6 mg**
- store at 20-25° C (68-77° F)
- AccuSafe[®] dosing device enclosed
- check expiration date on bottle or box before using

Inactive ingredients

benzoic acid, carboxymethylcellulose, glycerin, natural berry flavor, microcrystalline cellulose, sucrose, sodium benzoate, water, xanthan gum

Questions?

1-800-54-8853 Mon. – Fri. 8:00 a.m.to 8:00 p.m. EST

LittleRemedies.com

PRINCIPAL DISPLAY PANEL

Little Remedies®
INFANT

FEVER+PAIN RELIEVER
Acetaminophen 160 mg / 5 mL

natural berry flavor
2 FL OZ (59 mL)



LITTLE REMEDIES INFANT FEVER/PAIN RELIEVER

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:630 29 -6 10
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

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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:63029-610-01	1 in 1 BOX	07/01/2011	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63029-610-02	2 in 1 CARTON	07/01/2011	
2		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

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)