

LITTLE REMEDIES INFANT FEVER AND PAIN RELIEVER NATURAL BERRY NATURAL BERRY- acetaminophen liquid
Denison Pharmaceuticals, 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 Berry Fever Pain Reliever

Active ingredient

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 reactions 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.

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

Other information

- each 5 mL contains: sodium 6 mg
- Store at 20-25 °C (68-77 °F)
- AccuSafe® Oral 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?

For further information you may contact us at: **1-800-754-8853** Mon. – Fri. 8:00 a.m.to 8:00 p.m. EST, www.LittleRemedies.com.

PRINCIPAL DISPLAY PANEL

Approved for proof Chris Rankin 8/8/19

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LITTLE REMEDIES
Everything they need. Nothing they don't.®

INFANT FEVER + PAIN RELIEVER

NEW GREAT TASTE **INFANTS** **EFFECTIVE FOR FEVERS** **INFANTS**

LITTLE REMEDIES
Everything they need. Nothing they don't.®

LITTLE REMEDIES
Little Remedies® believes "less is more" and makes each of our products with the fewest and best ingredients we can use without sacrificing the product's effectiveness.

INFANT FEVER + PAIN RELIEVER
Acetaminophen 160mg / 5mL

No High Fructose Corn Syrup or Saccharin
No Ibuprofen or Aspirin

No Artificial Sweeteners, Flavors or Dyes
Paraben, Gluten, and Alcohol Free
natural berry flavor
2 FL OZ (59 mL)

Drug Facts
Active ingredient (in each 5.0 mL) **Purpose**
Acetaminophen 160 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
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 the child has liver disease.
Ask a doctor or pharmacist before use if the 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) right away. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Drug Facts (continued)
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 on side panel. (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 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
■ replace cap tightly to maintain child resistance
mL=milliliter

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

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

Inactive ingredients
benzoic acid, carbonylmethylcellulose, glycerin, natural berry flavor, microcrystalline cellulose, sucrose, sodium benzoate, water, xanthan gum

Questions? 1-800-754-8853 Mon.-Fri. 8:30 am to 5:30 pm EST
LittleRemedies.com

7 56184 10176 6

4 Color

Pantone 485

Pantone 273

LITTLE REMEDIES INFANT FEVER AND PAIN RELIEVER NATURAL BERRY NATURAL BERRY

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-9002
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
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	

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:0295-9002-12	1 in 1 BOX	04/18/2019	

1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product	
2	NDC:0295-9002-17	1 in 1 BOX	04/18/2019
2		118 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	04/18/2019	

Labeler - Denison Pharmaceuticals, Inc. (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, Inc.		001207208	manufacture(0295-9002)

Revised: 4/2019

Denison Pharmaceuticals, Inc.