

PEDIACARE INFANTS FEVER REDUCER DYE FREE- acetaminophen liquid
Blacksmith Brands, 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.

PediaCare Infants Fever Reducer Dye Free

Drug Facts

Active Ingredients

(in each 0.8 mL)

Acetaminophen 80mg

Purpose

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - sore throat
 - toothache
 - headache

Warnings

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

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

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 product 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 dose.

(see overdose warning)

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- 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) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **do not give more than directed (see overdose warning)**
- **shake well before use**
- **this product does not contain directions or complete warnings for adult use**
- use only with enclosed dosing device
- fill to dose level
- dispense liquid slowly into child's mouth towards inner cheek
- repeat dose every 4 hours if needed
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- use dropper to close bottle and maintain child resistance
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (yr)	Dose (mL)
Under 24	Under 2	ask a doctor
24-35	2-3	1.6 mL (0.8 + 0.8 mL)

Other information

store between 20-25°C (68-77°F)

Inactive ingredients:

butyl paraben, citric acid, flavor, glycerin, maltitol, propylene glycol, propyl paraben, purified water, sucralose, xanthan gum.

Questions or comments?

call **1-888-474-3099**

Distributed by:

Blacksmith Brands Inc.
 200 White Plains Road
 Tarrytown, NY 10591 USA
 © 2010

PRINCIPAL DISPLAY PANEL

NEW PediaCare® Infants
 Fever Reducer Pain Reliever
 Dye Free Ludens® Cherry Taste!
 1 FL OZ (30 mL)

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each 0.8 mL) Purpose
 Acetaminophen 80 mg.....Pain reliever/fever reducer

Uses temporarily:
 ■ reduces fever
 ■ relieves minor aches and pains due to:
 ■ the common cold ■ sore throat
 ■ flu ■ toothache
 ■ headache

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if the child takes
 ■ more than 5 doses in 24 hours, which is the maximum daily amount
 ■ with other drugs containing acetaminophen.
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 product 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 dose (see overdose warning)

Stop use and ask a doctor if
 ■ pain gets worse or lasts more than 5 days
 ■ fever gets worse or lasts more than 3 days
 ■ new symptoms occur
 ■ 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) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions
 ■ do not give more than directed (see overdose warning)
 ■ shake well before use
 ■ this product does not contain directions or complete warnings for adult use
 ■ use only with enclosed dosing device
 ■ fill to dose level
 ■ dispense liquid slowly into child's mouth towards inner cheek
 ■ repeat dose every 4 hours if needed
 ■ do not give more than 5 times in 24 hours
 ■ do not give for more than 5 days unless directed by a doctor
 ■ use dropper to close bottle and maintain child resistance
 ■ find right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (yr)	Dose (mL)
Under 24	Under 2	ask a doctor.
24-35	2-3	1.6mL (0.8 + 0.8 mL)

Other information
 ■ store between 20-25°C (68-77°F)

Inactive ingredients: butyl paraben, citric acid, flavor, glycerin, maltitol, propylene glycol, propyl paraben, purified water, sucralose, xanthan gum.

Questions or comments?
 call 1-888-474-3099

Distributed by:
 Blacksmith Brands Inc.
 200 White Plains Road
 Tarrytown, NY 10591 USA
 © 2010

New

PediaCare®

Infants

Fever Reducer
Pain Reliever

Drops for Infants
Acetaminophen

Alcohol Free • Aspirin Free • Ibuprofen Free

Dye Free Non-Staining

LUDENS®

Cherry Taste!

1 FL OZ (30 mL)

PediaCare®

Infants

Fever Reducer
Pain Reliever

PediaCare® medicines provide effective relief for your infant's cough, cold or allergy symptoms. PediaCare® Infants products come in great-tasting flavors your kids will love!

PediaCare.®
Just what they need.™

KEEP THIS BOX FOR COMPLETE INSTRUCTIONS.

MFR# 53041 REV 0610

8 14832 01094 2

PEDIACARE INFANTS FEVER REDUCER DYE FREE

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-383
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg in 0.8 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPII1U3FV8)	
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-383-01	1 in 1 BOX		
1		30 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/28/2010	

Labeler - Blacksmith Brands, Inc. (021411299)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE

Revised: 10/2010

Blacksmith Brands, Inc.