

BABIES R US PAIN AND FEVER- acetaminophen suspension

Toys "R"Us, 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.

Toys "R" Us, Inc. Infants' Pain & Fever 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 due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - 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

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

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child has ever had an allergic reaction to this product or any of its ingredients

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 does (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

- 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
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Firmly push syringe into bottle opening.
- turn bottle upside down. Pull syringe to the first dose line and then push product back into bottle.
- pull syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart			
Weight (lb)	Age (yr)	Dose (mL)*	
under 24	under 2 years	ask a doctor	
24-35	2-3 years	5 mL	

*or as directed by a doctor

Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

Other information

- store at 20-25°C (68-77°F)
- do not use if printed bottle wrap is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions?

1-800-719-9260

Package/Label Principal Display Panel

Infants' Pain & Fever

Acetaminophen Suspension

Fever Reducer – Pain Reliever

Aspirin Free

Ibuprofen Free

Alcohol Free

Cherry Flavor

Use only with enclosed syringe

See side panel for more information

See New Dosage & Directions

Pediatrician Preferred Dosing System

Compare to the active ingredient of Infants' Tylenol® Oral Suspension

1 fl oz (30 mL) 160 mg per 5 mL



BABIES R US PAIN AND FEVER			
acetaminophen suspension			
Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:51334-161
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	160 mg in 5 mL
Inactive Ingredients			

Ingredient Name	Strength
ANHYDRO US CITRIC ACID	
BUTYL PARABEN	
CALCIUM SULFATE	
CARRAGEENAN	
FD&C RED NO. 40	
GLYCERIN	
HIGH FRUCTOSE CORN SYRUP	
CELLULOSE, MICROCRYSTALLINE	
CARBOXYMETHYLCELLULOSE SODIUM	
PROPYLENE GLYCOL	
WATER	
SODIUM BENZOATE	
SORBITOL	
SODIUM PHOSPHATE, TRIBASIC	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51334-16 1-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		
2	NDC:51334-16 1-16	1 in 1 CARTON		
2		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	11/29/2011	

Labeler - Toys "R" Us, Inc. (006985808)

Revised: 1/2014

Toys "R" Us, Inc.