# BABIES R US PAIN AND FEVER- acetaminophen liquid 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

Fever reducer/pain reliever

#### 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

#### 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.

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 Liver warning)
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed syringe designed for use with this product. Do not use any other dosing device.
- remove bottle cap and insert syringe tip through opening at top of the bottle
- tip the bottle upside down and draw medicine into the syringe
- fill to dose level
- dispense liquid slowly into child's mouth, toward inner cheek
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- 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	

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 no. 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 Liquid

Fever Reducer – Pain Reliever

Aspirin Free

Ibuprofen Free

Alcohol Free

Cherry Flavor

Use only with enclosed syringe

See New Dosage & Directions

Pediatrician Preferred Dosing System

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

160 mg per 5 ml

# Infants' Pain & Fever

Acetaminophen - Suspension Liquid Fever Reducer - Pain Reliever

NDC 51334-161-10



# Infants' Pain & Fever

Acetaminophen - Suspension Liquid Fever Reducer - Pain Reliever

> Aspirin Free Ibuprofen Free Alcohol Free



Cherry Flavor

Use only with enclosed syringe

See New Dosage & Directions

Pediatrician Preferred Dosing System

Compare to the active ingredient of Infants' Tylenol® Suspension Liquid\*

# Directions:

- 1 Insert the syringe tip through the opening at the top of the bottle
- 2 Tip the bottle upside down and draw the medicine into the syringe
- 3 For ages 2 to 3 years, fill the syringe to the 5 mL line

Consult a doctor for dosage for children under 2 years old.

#### IMPORTANT:

Use enclosed syringe ONLY. DO NOT USE other cups or spoons.

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Suspension Liquid.





# 1 fl oz (30 ml) 160 mg per 5 ml

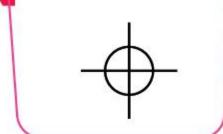
# www.babiesrus.com

BABIES "R" US is a registered trademark of Geoffrey, LLC. Part of the "R Us" Family of Brands.
© 2010 Geoffrey, LLC. All rights reserved.
Distributed by Toys "R" Us, Inc., Wayne, NJ 07470

LOT NO.

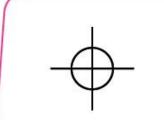
EXP.

: TPTTO MC CT



Infants' Pain & Fever Carton Image 1





# **Drug Facts**

# Active ingredient (in each 5 mL)

Purposes

Acetaminophen 160 mg......Fever reducer/pain reliever

the common cold

#### **Uses** temporarily:

- reduces fever
- relieves minor aches and pains due to:
  - 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

#### 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. 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 Liver warning)
- find right dose on chart. If possible, use weight to dose; otherwise use age. shake well before using
- use only enclosed syringe designed for use with this product. Do not use any other dosing device.

# Drug Facts (continued)

- remove bottle cap and insert syringe tip through opening at top of the bottle
- tip the bottle upside down and draw medicine into the syringe
- fill to dose level
- dispense liquid slowly into child's mouth, toward inner cheek
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- 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	

Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosina 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 no. 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





Infants' Pain & Fever Carton Image 2

## **BABIES R US PAIN AND FEVER**

acetaminophen liquid

Prod	net I	nform	nation
PIOU			IAIIOII

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:51334-161Route of AdministrationORALDEA Schedule

**Active Ingredient/Active Moiety** 

Ingredient Name
Basis of Strength
ACETAMINOPHEN (ACETAMINOPHEN)
ACETAMINOPHEN 160 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US CITRIC ACID	
BUTYLPARABEN	
CALCIUM SULFATE	
CARRAGEENAN	
FD&C RED NO. 40	
GLYCERIN	
HIGH FRUCTOSE CORN SYRUP	
CELLULOSE, MICRO CRYSTALLINE	
CARBO XYMETHYLCELLULO SE SODIUM	
PROPYLENE GLYCOL	
WATER	
SO DIUM BENZO ATE	
SORBITOL	
SO DIUM PHO SPHATE, 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:51334-161-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		
2	NDC:51334-161-16	1 in 1 CARTON		
2		60 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: 9/2012 Toys"R"Us, Inc.