

INFANTS PAIN AND FEVER- acetaminophen suspension
Rugby Laboratories, 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.

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- temporarily 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

Allergy alert: Acetaminophen may cause severe skin reactions. symptoms may include:

- skin reddening
- blisters
- rash

If a 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, 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 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

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

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 (1-800-222-1222) right away. 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 take more than directed (see overdose warning)**
- **shake well before using**
- mL= milliliter
- only use the enclosed syringe.

Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child

- remove cap, insert syringe into hole at top of bottle and turn upside down
- pull back syringe until filled to be prescribed level. If you pass the prescribed level, simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards 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 more than 5 days unless directed by a doctor
- replace cap tightly to maintain child resistance
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age

Weight (lb)	Age (year)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL

*or as directed by a doctor

Other information

- store between 20-25°C (68-77°F)
- do not refrigerate.
- see bottom panel for lot number and expiration date

Inactive ingredients

acesulfame potassium, butylparaben, carboxymethylcellulose sodium, citric acid, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

ASPIRIN & ALCOHOL FREE

****COMPARE TO THE ACTIVE INGREDIENT IN INFANTS' TYLENOL® ORAL SUSPENSION**

RELIEVES • INFANTS'

Pain and Fever

Acetaminophen 160 mg per 5 mL Oral suspension

Pain reliever / Fever reducer

- Alcohol free
- Aspirin free
- ibuprofen free

For ages 2-3 years

Cherry flavor

Use only enclosed syringe

FL OZ (mL)

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

Distributed by:

Rugby Laboratories

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Package Label

Drug Facts

Active ingredient (in each 5 mL) **Purpose**
Acetaminophen 160 mg **Pain reliever/fever reducer**

Uses ■ temporarily reduces fever
 ■ temporarily 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
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
 ■ skin redness ■ blisters ■ rash
 If a 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, 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 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 ■ new symptoms occur
 ■ redness or swelling is present
 ■ pain gets worse or lasts more than 5 days
 ■ fever gets worse or lasts more than 3 days
 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 (1-800-222-1222) right away. 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 take more than directed (see Overdose warning)
 ■ shake well before using

Drug Facts (continued)

■ mL = milliliter
 ■ only use the enclosed syringe.
Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.
 ■ remove cap and insert syringe into hole at top of bottle and turn upside down
 ■ pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards 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 more than 5 days unless directed by a doctor
 ■ replace cap tightly to maintain child resistance
 ■ find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (year)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL

*or as directed by a doctor

Other information
 ■ store between 20-25°C (68-77°F)
 ■ do not refrigerate
 ■ see bottom panel for lot number and expiration date

Inactive ingredients acasulfate potassium, butylparaben, carboxymethylcellulose sodium, citric acid, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?
 Call 1-877-753-3835
 Monday-Friday 9AM-5PM EST

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

NDC 0536-1111-96

ASPIRIN & ALCOHOL FREE

**COMPARE TO THE ACTIVE INGREDIENT IN INFANTS' TYLENOL® ORAL SUSPENSION

Rugby®

RELIEVES • INFANTS'
Pain & Fever

Acetaminophen 160 mg per 5 mL
Oral suspension

Pain reliever/Fever reducer

• Alcohol free
 • Aspirin free • Ibuprofen free
For ages 2-3 years

Use only enclosed syringe

CHERRY FLAVORED
2 fl oz (59 mL)

FLD-R2680 FDC03511

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

Distributed by:
Rugby Laboratories
 17177 N Laurel Park Drive, Suite 233
 Livonia, MI 48152
 www.rugbylaboratories.com

Re-Order No. 370466
 Rev. 8/16 R-58



RUGBY Infants' Pain & Fever Relief Cherry Flavor

INFANTS PAIN AND FEVER			
acetaminophen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1111
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		
BUTYLPARABEN (UNII: 3QP1U3FV8)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			

HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1111-96	1 in 1 BOX	04/30/2016	
1		59 mL in 1 BOTTLE, PLASTIC; 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	04/30/2016	

Labeler - Rugby Laboratories, Inc. (079246066)