

RUGBY ACETAMINOPHEN- acetaminophen liquid

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.

Rugby® Pain & Fever ACETAMINOPHEN ORAL SOLUTION

Drug Facts

Active ingredient (in each 5mL)

Acetaminophen 160 mg

Purpose

Pain reliever-Fever reducer

Uses

temporarily reduces fever and relieves minor aches and pains caused by

- 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 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

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms appear
- 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 (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**
- find right dose on chart. If possible, use weight to dose; otherwise, use age
- give dose every 4 hours while symptoms last
- do not give more than 5 doses in 24 hours
- use enclosed dosing cup only. Do not use with any other device.
- mL = milliliter

Weight	Age	Dose
72 - 95 lbs	11 years	15mL
60 - 71 lbs	9 - 10 years	12.5mL
48 - 59 lbs	6 - 8 years	10mL
36 - 47 lbs	4 - 5 years	7.5mL
24 - 35 lbs	2 - 3 years	5mL
under 24 lbs	under 2 years	ask a doctor

Other information

- each 5 mL contains: **sodium 1 mg**
- store at 20 - 25°C (68 - 77°F)

Inactive ingredients

artificial flavor, citric acid anhydrous, D&C Red #33, FD&C Red #40, glycerin, polyethylene glycol 1450, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol.

Questions or comments?

1-800-645-2158

Distributed by: **Rugby Laboratories**
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

Rugby®

NDC 0536-0122-97

RELIEVES CHILDREN'S

Pain

& Fever

ACETAMINOPHEN

ORAL SOLUTION

CHERRY FLAVORED

SUGAR FREE

Aspirin & Alcohol Free

4 fl oz (118 mL) 160mg per 5mL

COMPARE TO THE INGREDIENT IN CHILDREN'S TYLENOL®. Do not use if inner seal over mouth of bottle is broken or missing.

Drug Facts

Active ingredient
(in each 5mL)
Acetaminophen 160 mg.....Pain reliever-Fever reducer

Purpose
● temporarily reduces fever and relieves minor aches and pains
● common cold ● flu ● headache ● sore throat ● toothache

Uses
Temporarily reduces fever and relieves minor aches and pains

Warnings
Lower warnings: 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: ● pain gets worse or lasts more than 5 days ● fever gets worse or lasts more than 3 days ● new symptoms appear ● redness or swelling is present. These could be signs of a serious condition.

Distributed by: Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com
Rev. 08/16 Re-order No. 370014 R-64 3 05360 12297 4

LOT/EXP

SPOT UV

PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

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.

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Questions or comments?
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*Rugby is not affiliated with the owner of the trademark Tylenol®.

RUGBY ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-0122
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
GLYCERIN (UNII: PDC6A3C0OX)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0K00R)	
SUCROSE (UNII: C151H8M554)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHERRY (UNII: BUC5I9595W)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-0122-97	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2011	01/31/2021
2	NDC:0536-0122-85	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2011	01/31/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/28/2011	01/31/2021

