

**CHILDRENS ACETAMINOPHEN- acetaminophen elixir**  
**Rij Pharmaceutical Corporation**

*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.*

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**CHILDRENS ACETAMINOPHEN**

**Active ingredient (in each 5 mL = 1 teaspoonful)**

Acetaminophen 160 mg

**Active ingredient (in each 5 mL = 1 teaspoonful)**

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
  - immunizations
  - 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 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 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.**
- **shake well before using**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- if needed, repeat dose every 4 hours
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

<b>Weight (lbs.)</b>	<b>Age (yrs.)</b>	<b>Dose (tsp or mL)</b>
under 24	under 2	ask a doctor
24-35	2-3 years	1 tsp or 5 mL
36-47	4-5 years	1½ tsp or 7.5 mL
48-59	6-8 years	2 tsp or 10 mL
60-71	9-10 years	2½ tsp or 12.5 mL
72-95	11 years	3 tsp or 15 mL

**Other information**

- Store at room temperature 15° - 30°C (59° - 86°F)
- Protect from Freezing.
- Protect from Light.
- each teaspoon (5 mL) contains: sodium 7 mg
- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING**

**Inactive ingredients**

citric acid, FD&C red # 40, flavor, glycerin. polyethylene glycol, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water.

**PRINCIPAL DISPLAY PANEL**



NDC 53807-129-04

**CHILDREN'S  
NON-ASPIRIN  
(Acetaminophen)  
ELIXIR  
ALCOHOL FREE**

Relieves Children's Fever  
and Pain

\*Compare to active ingredients  
of Tylenol® Elixir

**4 FL. OZ. (118 mL)**

RIJ PHARMACEUTICAL CORPORATION  
40 COMMERCIAL AVENUE  
MIDDLETOWN, NY 10941

**Drug Facts**

**Active ingredient** (in each 5mL = 1 teaspoon)  
**Acetaminophen 160 mg**.....**Pain reliever / Fever reducer**

**Uses temporarily:** ■ reduces fever ■ relieves minor aches and pains due to: ■ the common cold ■ flu ■ headache ■ sore throat ■ immunizations ■ 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 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 for more than 5 days ■ fever gets worse or lasts for 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 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 ■ shake well before using ■ find right dose on chart below. If possible, use weight to dose; otherwise, use age. ■ if needed, repeat dose every 4 hours ■ do not use more than 5 times in 24 hours ■ do not give more than 5 days unless directed by a doctor.

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**Other information** ■ Store at room temperature, 15°-30° C (59°-86° F) ■ Protect from Freezing ■ Protect from Light ■ Each teaspoon (5mL) contains: sodium 7 mg

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING.**

**Inactive ingredients:** citric acid, FD&C red #40, flavor, glycerin, polyethylene glycol, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water.

\*This product is not manufactured or distributed by the owner of the registered trademark Tylenol® L.R. Rev. 12/904-0910



# CHILDRENS ACETAMINOPHEN

acetaminophen elixir

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53807-129
<b>Route of Administration</b>	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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

## Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (CHERRY)	<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-129-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-129-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
3	NDC:53807-129-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
4	NDC:53807-129-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
5	NDC:53807-129-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
6	NDC:53807-129-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	03/16/1999	

**Labeler** - Rij Pharmaceutical Corporation (144679156)**Establishment**

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-129)

Revised: 4/2018

Rij Pharmaceutical Corporation