CHILDRENS ACETAMINOPHEN- acetaminophen suspension
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.

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

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 use more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor
- only use enclosed measuring cup

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

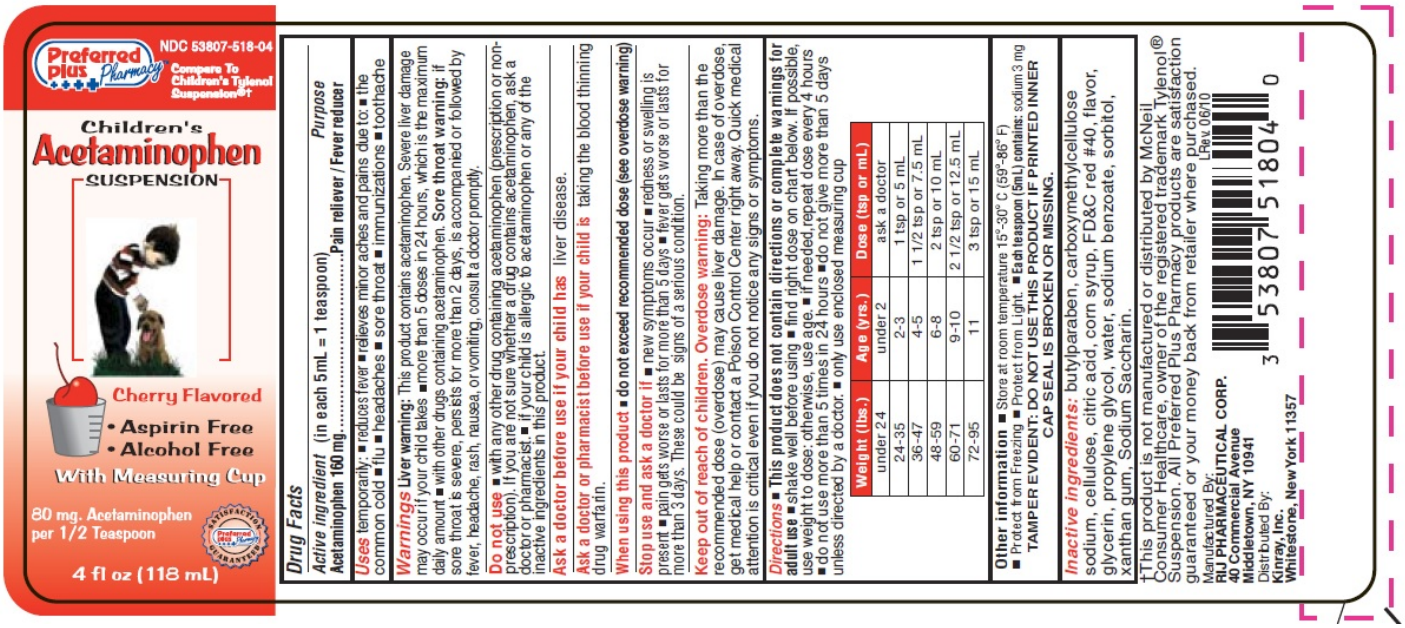
Other information

- Store at room temperature 15º - 30ºC (59º - 86ºF)
- Protect from Freezing.
- Protect from Light.
- each teaspoon (5 mL) contains: sodium 3 mg
- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING**

Inactive ingredients

butylparaben, carboxymethylcellulose sodium, cellulose, citric acid, corn syrup, FD&C red # 40, flavor, glycerin, propylene glycol, water, sodium benzoate, sorbitol, xanthan gum, Sodium saccharin.

PRINCIPAL DISPLAY PANEL



CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53807-518
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: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CORN SYRUP (UNII: 9G5L16BK6N)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	CHERRY (GRAPE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-518-04	118 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(53807-518)

Revised: 4/2018 Rij Pharmaceutical Corporation