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.

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 for adults as well as for children 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
- only use enclosed measuring cup

Weight (lbs.)	Age (yrs.)	Dose (tsp or mL)
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

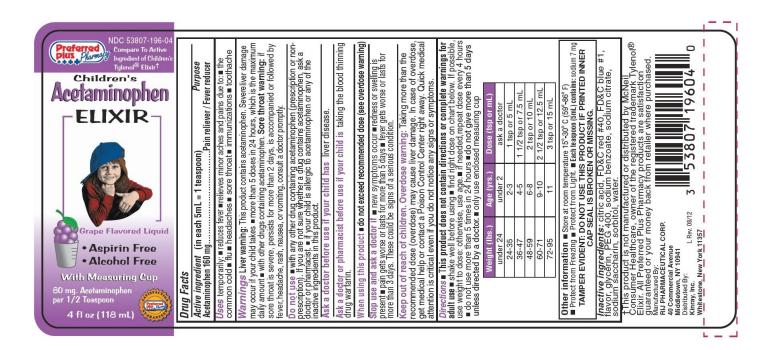
Other information

- 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, FD&C blue # 1, flavor, glycerin. PEG 400, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water.

PRINCIPAL DISPLAY PANEL



CHILDRENS ACETAMINOPHEN

acetaminophen elixir

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-196
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		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	

Flavor	(GRAPE (GRAPE)	Imprint Code	
Contains				
Packaging				
# Item Code		Package Description	Marketing Start Date	Marketing End Date
1 NDC:53807-196-04	118 mL i	n 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
Marketing Information				
Marketing Categ	gory	Application Number or Monograph Citati	on Marketing Start Date	Marketing End Date
OTC MONOGRAPH NO	T FINAL	part343	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rij Pharmaceutical Corporation		144679156	manufacture(53807-196)	

Revised: 4/2018 Rij Pharmaceutical Corporation