

ACETAMINOPHEN- acetaminophen liquid
SAMJAN GROUP 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.

Active ingredient (per 5mL teaspoonful)

Acetaminophen 160 mg

Pain Reliever / Fever Reducer

Uses

temporarily • relieves minor aches • reduces fever

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 • taken 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.

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 a 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.

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 occur

- redness or swelling is present. These could be signs of a serious condition.

Keep out of reach of children.

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

- **do not take more than directed**

This product does not contain directions or complete warnings for adult use.

- find dose in chart below, if possible, use weight to dose, otherwise use age
- dosage may be repeated every 4 hours as needed, or as directed by a doctor
- do not give more than 5 doses in 24 hours • 5 milliliters (mL) = 1 teaspoon

Weight (lb)	Under 24	24-36	36-47	48-59	60-71	72-95
age (yr)	Under 2	2-3	4-5	6-8	9-10	11
Dosage (mL)	ask a doctor	5 mL	7.5 mL	10 mL	12.5 mL	15 mL

Other information

- each teaspoonful (5 mL) contains: sodium 7.9 mg
- store at room temperature 15°- 30°C (59°-86°F)
- protect from freezing • protect from light
- **TAMPER-EVIDENT:** Do not use if imprinted seal under cap is broken or missing.

Inactive ingredients:

artificial cherry flavor, citric acid, FD&C Red #40, glycerin, PEG, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol.

PRINCIPAL DISPLAY PANEL

- Compare To Active ingredient of Children's Tylenol

NDC 72091-004-01

Children's Liquid

Pain Reliever and Fever Reducer

Acetaminophen 160 mg/5mL

- Aspirin Free
- Alcohol Free

- For Children Ages 2 - 11 years

Fruit Flavor

8 FL OZ (237 mL)

Drug Facts

Active ingredient (per 5mL teaspoonful) Acetaminophen (160mg)

Purpose Pain Reliever / Fever Reducer

Uses temporarily • relieves minor aches • reduces fever

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ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72091-004
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 MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72091-004-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/17/2021	

Labeler - SAMJAN GROUP INC. (080313200)

Revised: 3/2021

SAMJAN GROUP INC.