LIQUID ACETAMINOPHEN- acetaminophen liquid
LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION

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 5 mL teaspoonful)

Acetaminophen 160 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

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.

Ask a doctor before use if you have liver disease.

Ask a doctor before use if you are 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 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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.

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children. In case of overdose, get medical help or contact a Paoison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**
- find dose in chart below
- if possible, use weight to dose, otherwise use age
- dosage may be repeasted every 4 hours, or as directed by a doctor
- do not give more than 5 doses in 24 hours

Weight (lbs)	under 24	24-35	36-47	48-59	60-71	72-95	over 95
Age (years)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11	12 to adult
Dosage Teaspoonful (tsp)	consult Physician	1 tsp (5 mL)	1 1/2 tsp (7.5 mL)	2 tsp (10 mL)	2 1/2 tsp (12.5 mL)	3 tsp (15 mL)	4 tsp (20 mL)

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

LIQUID ACETAMINOPHEN

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-809
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**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54859-809-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/01/2019	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Registrant - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

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