ACETAMINOPHEN- acetaminophen liquid
NuCare Pharmaceuticals,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.

Acetaminophen

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Acetaminophen, USP 160 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver Warning

This product contains acetaminophen.

Severe liver damage may occur if you take:
- more than 8 teaspoonfuls (40 mL) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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.

Ask a doctor before use

if you have health issues especially liver disease.

Ask a doctor or pharmacist before use

if you are taking other drugs, including the blood thinner warfarin.

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.

- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Stop use and ask a doctor if

- new symptoms occur such as rash, hives, itching or hoarseness
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- symptoms do not improve

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 Poison Control Center right away. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

Do not exceed recommended dosage.

Overdose Warnings

Taking more than the recommended dose (overdose) can cause serious health problems, including liver damage.

- **adults and children 12 years of age and older:** take 2 teaspoonfuls (10 mL) every 6 hours; do not exceed 8 teaspoonfuls (40 mL) in 24 hours
- **children under 12 years of age:** Under the direct guidance of a licensed professional, doctor, or pharmacist.

Other information

If dispensed, dispense in a tight, light resistant container with a child-resistant cap.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C

(between 59°F and 86°F)

Inactive ingredients

Bitter Mask, Cherry Flavor, Citric Acid, FD&C Red No. 40, Glycerin, Polyethylene Glycol, Purified Water, Sodium Benzoate,Sodium Citrate Dihydrate, Sodium Saccharin, Sorbitol.

Questions?

You may report side effects by calling Westminster M-F (9 a.m. to 5 p.m. EST), at 1-844-7294 or FDA at 1-800-FDA-1088.

PRINCIPAL DISPLAY PANEL -

ACETAMINOPHEN

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-2870(NDC:69367-323)
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2870-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/05/2021	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2870)

Revised: 11/2022 NuCare Pharmaceuticals,Inc.