# ACETAMINOPHEN- acetaminophen tablet 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.

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#### Major Pharmaceuticals Acetaminophen Drug Facts

# **Active ingredient (in each caplet)**

Acetaminophen 500 mg

# **Purpose**

Pain reliever/fever reducer

#### Uses

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

#### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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.

#### 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 you have ever had an allergic reaction to this product or any of its ingredients

# Ask a doctor before use if you have

liver disease

## Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

#### Stop use and ask a doctor if

- pain gets worse or lasts more than 10 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.

## If pregnant or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul> <li>take 2 caplets every 6 hours while symptoms last</li> <li>do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>	
children under 12 years ask a doctor		

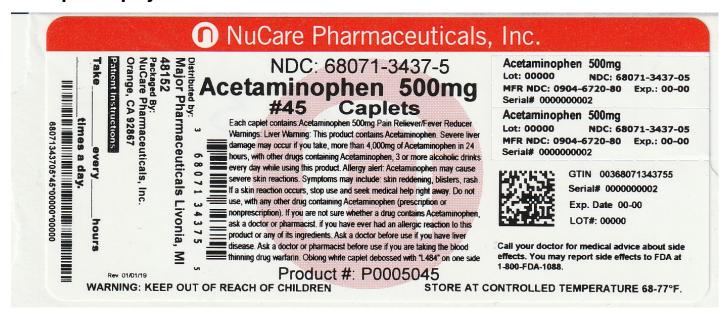
# **Inactive ingredients**

carnauba wax, corn starch\*, croscarmellose sodium\*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid

\*may contain one or more of these ingredients

#### **Questions or comments?**

#### **Principal Display Panel**



#### **ACETAMINOPHEN**

acetaminophen tablet

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-3437(NDC:0904-6720)

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 500 mg

Inactive Ingredients				
Ingredient Name	Strength			
CARNAUBA WAX (UNII: R12CBM0EIZ)				
STARCH, CORN (UNII: 08232NY3SJ)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				

Product Characteristics						
Color	white	Score	no score			
Shape	OVAL	Size	16mm			

Flavor	Imprint Code	L484
Contains		

Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68071- 3437-5	45 in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	07/26/2018		

# Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-3437)	

Revised: 6/2023 NuCare Pharmaceuticals,Inc.