

ACETAMINOPHEN- acetaminophen tablet
NuCare Pharmaceuticals, Inc.

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 style="list-style-type: none">• take 2 caplets every 6 hours while symptoms last• do not take more than 6 caplets in 24 hours, unless directed by a doctor• do not use for more than 10 days unless directed by a doctor
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?

1-800-616-2471

Principal Display Panel

NuCare Pharmaceuticals, Inc.

Distributed by: 3 6 8 0 7 1 3 4 3 7 5
 Major Pharmaceuticals Livonia, MI 48152
 Packaged By: NuCare Pharmaceuticals, Inc.
 Orange, CA 92867
 Patient Instructions: Take every hours times a day.
 Rev 01/01/19
 68071343705*45*00000*00000

NDC: 68071-3437-5 Acetaminophen 500mg #45 Caplets

Each caplet contains Acetaminophen 500mg Pain Reliever/Fever Reducer
 Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take more than 4,000mg 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. Oblong white caplet debossed with "L484" on one side

Product #: P0005045

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

Acetaminophen 500mg
 Lot: 00000 NDC: 68071-3437-05
 MFR NDC: 0904-6720-80 Exp.: 00-00
 Serial# 0000000002

Acetaminophen 500mg
 Lot: 00000 NDC: 68071-3437-05
 MFR NDC: 0904-6720-80 Exp.: 00-00
 Serial# 0000000002



GTIN 00368071343755
 Serial# 0000000002
 Exp. Date 00-00
 LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

ACETAMINOPHEN

acetaminophen tablet

Product Information

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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3S)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	L484
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3437-5	45 in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2023	
2	NDC:68071-3437-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2023	
3	NDC:68071-3437-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2026	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M013	07/26/2018	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

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