

ACETAMINOPHEN- extra strength pain relief tablet
NuCare Pharmaceuticals, Inc.

gc201

Active Ingredients

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains
- temporarily reduces fever

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets 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

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 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 symptom 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.

Overdose Warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Keep out of reach of children.

Directions

- **do not take more than directed**
- adults and children 12 years and over: take 1-2 tablets every 4-6 hours, as needed; not more than 8 tablets in 24 hours
- children under 12 years: do not use

Other Information

- **TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.**
- store at 20°C-25°C (68°F-77°F)
- for institutional use only

Inactive Ingredients

povidone, sodium starch glycolate, starch, stearic acid. May also contain: crospovidone, methylparaben and propylparaben

 NuCare Pharmaceuticals, Inc.

NDC: 68071-5239-3
Acetaminophen 500mg
#30 Tablets

Each tablet contains: Acetaminophen 500mg. Pain Reliever/Fever Reducer.
Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take: more than 8 tablets (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. 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. Round shape white tablet imprinted "M2A457344" on one side.

Product #: P0005030

Acetaminophen 500mg
Lot: 00000 NDC: 68071-5239-03
MFR NDC: 57896-201-10 Exp.: 00-00
Serial#: 0000000002

Acetaminophen 500mg
Lot: 00000 NDC: 68071-5239-03
MFR NDC: 57896-201-10 Exp.: 00-00
Serial#: 0000000002

GTIN 00368071523935
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.

Distributed by:
Gerl-Care Pharmaceuticals Corp.
Brooklyn, NY 11204
Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92667

Take _____ times a day, every _____ hours

6807152393-30 00000-00000

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

ACETAMINOPHEN

extra strength pain relief tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-5239(NDC:57896-201)
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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		
POVIDONE (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
CROSPVIDONE (UNII: 68401960MK)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	white (WHITE)	Score	no score	
Shape	ROUND (Round)	Size	12mm	
Flavor		Imprint Code	M2A457344	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-5239-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
2	NDC:68071-5239-5	45 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
3	NDC:68071-5239-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007		01/01/1989	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-5239)

