ACETAMINOPHEN- extra strength pain relief 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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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

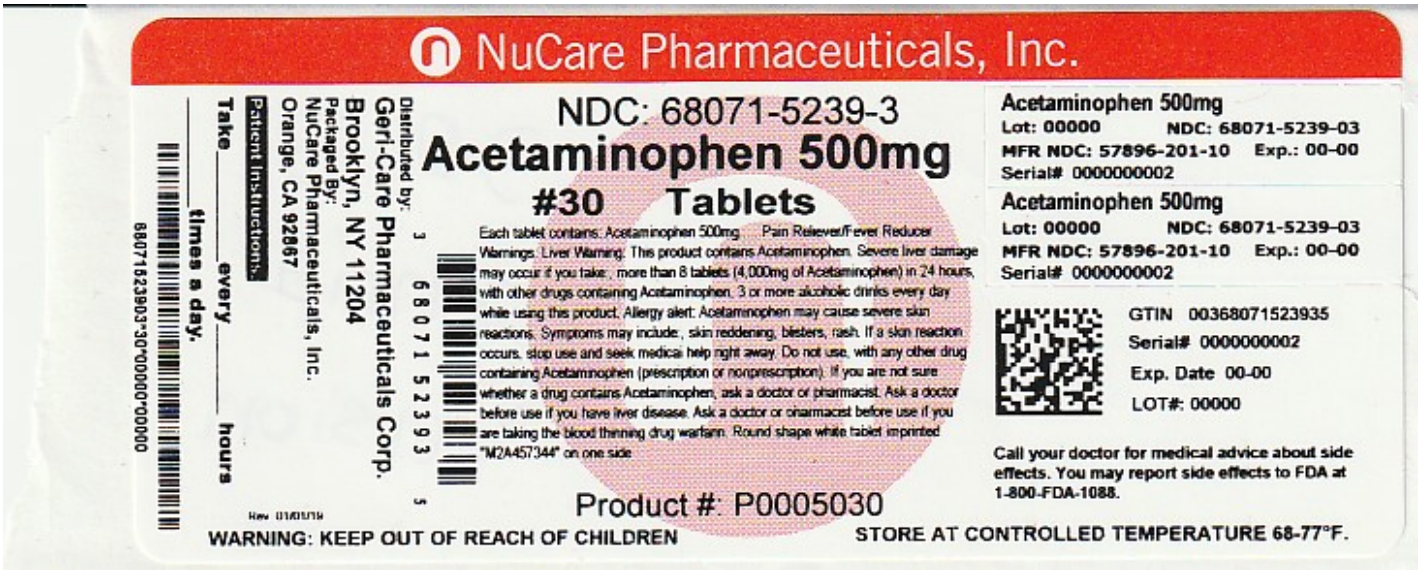
- **do not take more than directed**
- adults and children 12 years and over: take 1-2 tablets every 4-6 hours, as needed; not more than 8 tablets in 24 hours
- children under 12 years: do not use

Other Information

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

Inactive Ingredients

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



ACETAMINOPHEN
extra strength pain relief tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-5239(NDC:57896-201)
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)	
CROSPOVIDONE (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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/1989	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

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

Revised: 7/2023 NuCare Pharmaceuticals,Inc.