

**PLUSPHARMA EXTRA STRENGTH PAIN RELIEVER, FEVER REDUCER 500 MG-
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.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purposes

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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

These could be signs of a serious condition.

pain gets worse or lasts more than 10 days

fever gets worse or lasts more than 3 days

new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In the 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:

- 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 take for more than 10 days unless directed by a doctor

Children under 12 years: ask a doctor

Other information

- **Do not use if imprinted safety seal under cap is broken or missing.**
- Store at room temperature

Inactive ingredients

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

Principal Display Panel

Packaged By:
NuCare Pharmaceuticals, Inc
Orange, CA 92867

Patent Instructions:

Take _____ every _____ hours
_____ times a day.

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Distributed by:
Plus Pharma, Commack, NY 11725

NDC: 68071-4339-5
Acetaminophen 500mg
#45 Caplets

Each caplet contains: Acetaminophen 500mg.....Pain reliever/fever reducer
Warnings: Liver Warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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. 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 are allergic to acetaminophen or any of the inactive ingredients in this product, 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 "GPI A5" on one side

Product #: P0005045

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

Acetaminophen 500mg
Lot: 000000 NDC: 68071-4339-05
MFR NDC: 51645-705-01 Exp.: 00-00

Acetaminophen 500mg
Lot: 000000 NDC: 68071-4339-05
MFR NDC: 51645-705-01 Exp.: 00-00



GTIN 00368071433951
Serial# 00000000002
Exp. Date 00-00
LOT#: 000000

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

PLUSPHARMA EXTRA STRENGTH PAIN RELIEVER, FEVER REDUCER 500 MG

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-4339(NDC:51645-705)
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)	
STARCH, CORN (UNII: O8232NY3S)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (white biconvex caplet)	Size	5mm
Flavor		Imprint Code	GPI;A5
Contains			

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4339-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2018	
2	NDC:68071-4339-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2018	
3	NDC:68071-4339-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2018	
4	NDC:68071-4339-5	45 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2018	
5	NDC:68071-4339-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2018	
6	NDC:68071-4339-7	21 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/27/2006	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-4339)

Revised: 3/2021

NuCare Pharmaceuticals,Inc.