

**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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**gc101 (104)**

**Active Ingredients**

Acetaminophen 325 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 4,000 mg (12 tablets) 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.

**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.

**Keep out of reach of children.** 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.

**Directions**

- do not take more than directed
- adults and children 12 years and over: Take 2 tablets every 4-6 hours, as needed; not more than 10 tablets in 24 hours. Do not take for more than 10 days unless directed by a doctor.
- children under 12 years: ask a doctor

**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)

**Inactive Ingredients**

povidone, sodium starch glycolate, starch, stearic acid.

**Package Label**

**NuCare Pharmaceuticals, Inc.**

**NDC: 68071-2481-5**  
**Acetaminophen 325mg**  
**#50 Tablets**

Each tablet contains Acetaminophen 325mg. Pain Reliever/Fever Reducer  
 Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take more than 4,000mg (12 tablets) 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. 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. 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. Round white scored tablet debossed 44 104 on the scored side

Product #: P0003050

**WARNING: KEEP OUT OF REACH OF CHILDREN**      **STORE AT CONTROLLED TEMPERATURE 68-77°F.**

Acetaminophen 325mg  
 Lot: 00000      NDC: 68071-2481-05  
 MFR NDC: 57896-104-10      Exp.: 00-00  
 Serial# 000000002

Acetaminophen 325mg  
 Lot: 00000      NDC: 68071-2481-05  
 MFR NDC: 57896-104-10      Exp.: 00-00  
 Serial# 000000002

GTIN 00368071248159  
 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.

Rev 01/01/19

Take \_\_\_\_\_ times a day, every \_\_\_\_\_ hours

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

68071 2481 50 00000 00000

# ACETAMINOPHEN

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-2481(NDC:57896-104)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	white (WHITE)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (Round)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;104
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2481-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2021	
2	NDC:68071-2481-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2021	
3	NDC:68071-2481-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2021	
4	NDC:68071-2481-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2021	
5	NDC:68071-2481-7	25 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2020	

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**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-2481)

Revised: 9/2023

NuCare Pharmaceuticals, Inc.