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.

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves 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 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children.

Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has

liver disease

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 the reach of children.

Overdose warning:

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 tablets, every 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directe by a doctor • do not use for more than 10 days unless directed by a doctor
children 6 to under 12 years	• take 1 tablet every 4 to 6 hours while symptoms last • do not take more than 5 tablets in 24 hours • do not use for more than 5 days unless directed by a doctor

children under 6 years	ask a doctor

Other information

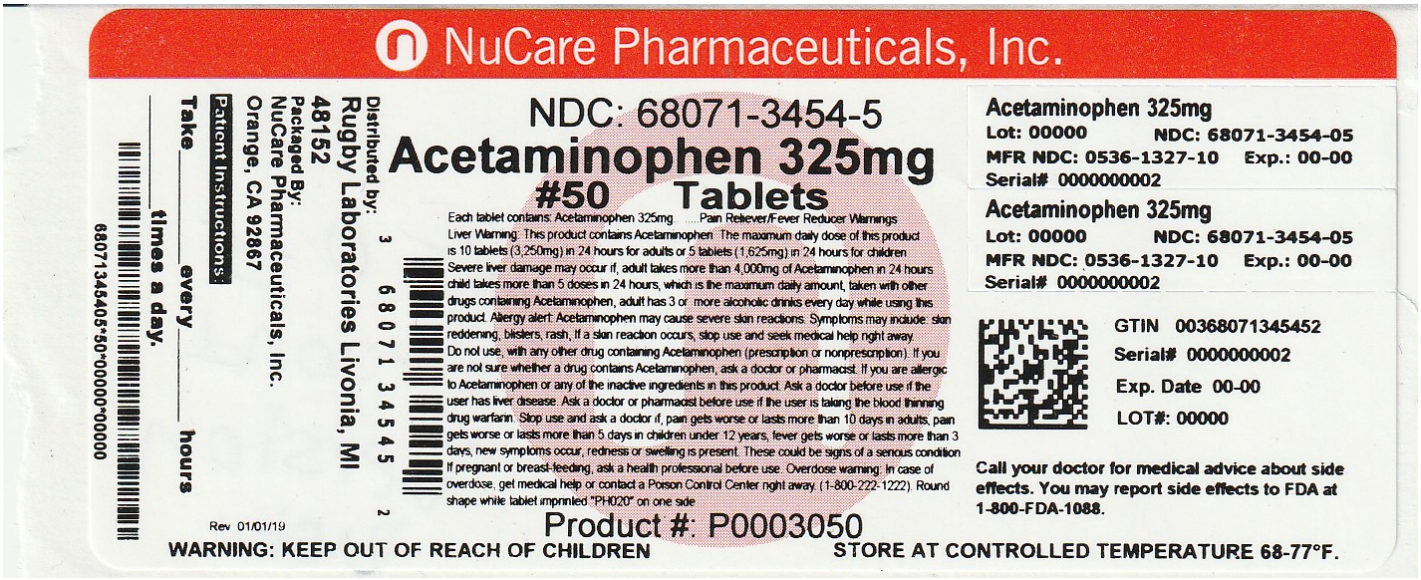
- store between 20-25°C (68-77°F)

Inactive ingredients

povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

Questions or comments?

1-800-645-2158



ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-3454(NDC:0536-1327)
Route of Administration	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)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	PH020
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3454-5	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/12/2023	
2	NDC:68071-3454-4	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/12/2023	
3	NDC:68071-3454-3	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/12/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/11/2021	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-3454)

Revised: 9/2023 NuCare Pharmaceuticals,Inc.