

ACETAMINOPHEN- acetaminophen tablet
NuCare Pharmaceuticals, Inc.

Major Pharmaceuticals Acetaminophen Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 mg

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. 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
- 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 the user has ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if the user

- has liver disease
- is a child with pain of arthritis

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 (for adults) or 5 days (for children)
- 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 reach of children.

Overdose warning: In 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	<ul style="list-style-type: none">• take 2 tablets every 4 to 6 hours while symptoms last• do not take more than 10 tablets in 24 hours• do not use for more than 10 days unless directed by a doctor
children 6-11 years	<ul style="list-style-type: none">• 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

Inactive ingredients

croscarmellose sodium*, povidone, pregelatinized starch, stearic acid

*may contain this ingredient

Questions or comments?

1-800-616-2471

Principal Display Panel

NuCare Pharmaceuticals, Inc.

Patent Instructions

Take _____ times a day, every _____ hours

Rev 01/01/19

NDC: 68071-2201-3

Acetaminophen 325mg

#30 Tablets

Each tablet contains: Acetaminophen,325mg Pain reliever/fever reducer
Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if, adult takes more than 4,000mg of Acetaminophen in 24 hours, child takes more than 5 doses in 24 hours, taken with other drugs containing Acetaminophen, adult has 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 the user has ever had an allergic reaction to this product or any of its ingredients. Ask a doctor before use if the user, has liver disease, is a child with pain of arthritis. 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 (for adults) or 5 days (for children), 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. Round White Scored Tablet Debossed: "325mg" on the scored side "L403" on the other side

Product #: P0003030

Acetaminophen 325mg
 Lot: 000000 NDC: 68071-2201-03
 MFR NDC: 0904-6719-60 Exp.: 00-00
 Serial# 0000000002

Acetaminophen 325mg
 Lot: 000000 NDC: 68071-2201-03
 MFR NDC: 0904-6719-60 Exp.: 00-00
 Serial# 0000000002

GTIN 00368071220131
 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.

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

ACETAMINOPHEN			
acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2201(NDC:0904-6719)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name		Basis of Strength
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN
			325 mg
Inactive Ingredients			
	Ingredient Name		Strength
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
	POVIDONE (UNII: FZ989GH94E)		
	STEARIC ACID (UNII: 4ELV7Z 65AP)		
Product Characteristics			
Color	white	Score	no score
Shape	ROUND (beveled edge)	Size	10mm
Flavor		Imprint Code	325MG;L403
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2201-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/18/2018	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-2201)

Revised: 7/2024

NuCare Pharmaceuticals, Inc.