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.

5427-Major

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/ Fever reducer

Uses

Temporarily reduces fever and relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- common cold
- toothache
- premenstrual and
- menstrual cramps

Liver warning: This product contains acetaminophen. 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

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.

- 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

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.

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:

• take 2 tablets every 6 hours while symptoms last

• do not take more than 6 tablets 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

store at room temperature

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

Call (800) 616-2471

SAVE CARTON FOR COMPLETE DRUG FACTS

Do not use if carton is open or if imprinted safety seal under cap is broken or missing.

Distributed By:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-2758(NDC:0904-6730)
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**
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	54;27
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:68071-2758-5	45 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2022	
2	NDC:68071-2758-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2022	
3	NDC:68071-2758-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/12/2018	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-2758)

Revised: 8/2022 NuCare Pharmaceuticals,Inc.