ACETAMINOPHEN 500 MG- acetaminophen tablet
NUVICARE LLC

Extra Strength Pain Relief ACETAMINOPHEN 500 mg

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

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.

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 ingredient in this product.

Ask a doctor before use if you have
- liver disease

Ask a doctor/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
- redness or swelling is present
- new symptoms occur

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 (1-800-222-1222) 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 (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 use for more than 10 days unless directed by a doctor

Children under 12 Years
- ask a doctor

Other information
- store at 20º - 25ºC (68º -77ºF)

Inactive ingredients

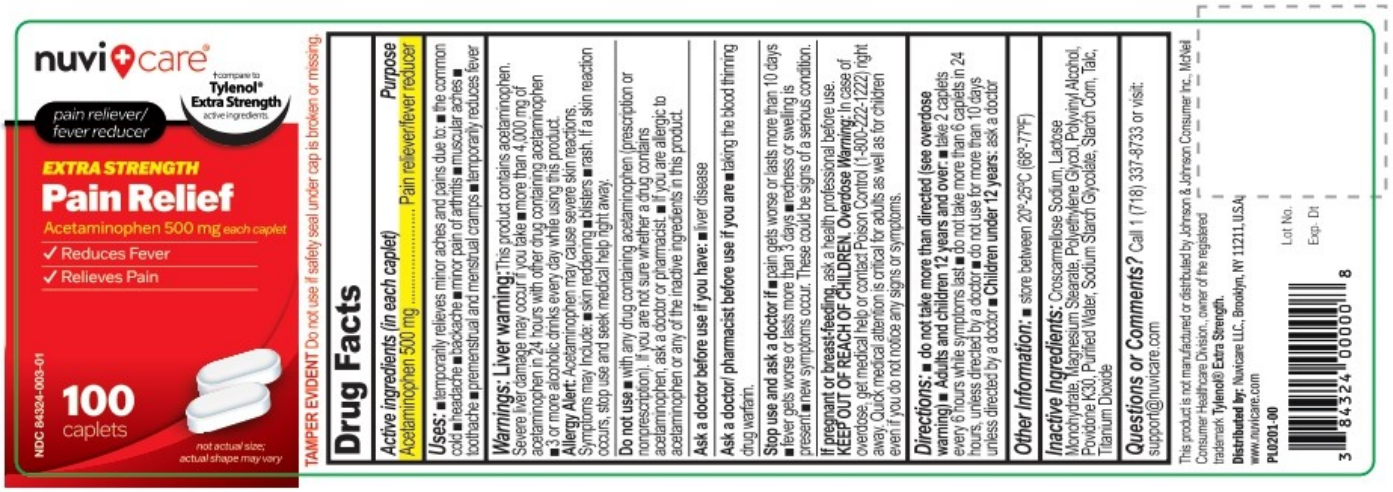
Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Alcohol, Povidone k30, Purified water, Sodium Starch Glycolate, Starch Corn, Talc, Titanium Dioxide

Questions or comments?

Call 1 (718) 337-8733 or visit: support@nuvicare.com

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc.,

McNeil Consumer Healthcare Division., owner of the registered trademark Tyleno® Extra Strength Caplets.



ACETAMINOPHEN 500 MG

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:84324-003
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	capsule	**Size**	17mm
Flavor		**Imprint Code**	P500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84324-003-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/17/2024	

Labeler - NUVICARE LLC (119257565)

Registrant - NUVICARE LLC (119257565)

Establishment

Name	Address	ID/FEI	Business Operations
TRUECARE BIOMEDIX		650526341	manufacture(84324-003)

Establishment

Name	Address	ID/FEI	Business Operations
MAK Pharma USA		109960731	pack(84324-003)

Revised: 7/2024 NUVICARE LLC