# ACETAMINOPHEN- acetaminophen tablet, coated RETAIL BUSINESS SERVICES, LLC.

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1004-CAR-2023-1102

**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
  - toothache
  - muscular aches
  - 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 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	<ul> <li>take 2 caplets every 6 hours while symptoms last</li> <li>do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	<ul><li>ask a doctor</li></ul>

#### Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

## **Inactive ingredients**

hypromellose, mineral oil, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

#### PRINCIPAL DISPLAY PANEL

**CAREone®** 

NDC 72476-104-01

Compare to the active ingredient in Tylenol® Extra Strength Caplets†

Extra Strength

**ACETAMINOPHEN** 

Pain Reliever / Fever Reducer

For Adults

**Actual Size** 

24 CAPLETS



#### **ACETAMINOPHEN**

acetaminophen tablet, coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72476-104

**Route of Administration** ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 500 mg

## **Inactive Ingredients**

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

mactive ingredients		
Ingredient Name	Strength	
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MINERAL OIL (UNII: T5L8T28FGP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
POVIDONE (UNII: FZ989GH94E)		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		
STEARIC ACID (UNII: 4ELV7Z 65AP)		

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	M2A4;57344

Contains

#### **Packaging**

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 1	NDC:72476- 104-01	1 in 1 CARTON	01/20/2023	
	1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing	Information
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/20/2023	

## Labeler - RETAIL BUSINESS SERVICES , LLC. (967989935)

Revised: 11/2023 RETAIL BUSINESS SERVICES , LLC.