# ACETAMINOPHEN- acetaminophen tablet CVS Pharmacy

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.

\_\_\_\_\_

## CVS Pharmacy, Inc. Acetaminophen 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 have ever had an allergic reaction to this product or any of its ingredients

## 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 ask a doctor		

#### Other information

• store at 20-25°C (68-77°F)

## **Inactive ingredients**

carnauba wax, corn starch\*, croscarmellose sodium\*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid

#### Questions or comments?

1-800-719-9260

<sup>\*</sup>may contain one or more of these ingredients

## **Principal Display Panel**

Compare to the active ingredient in Extra Strength  $Tylenol^{\circledR}$ 

Caplets

EXTRA STRENGTH

Acetaminophen Caplets 500 mg

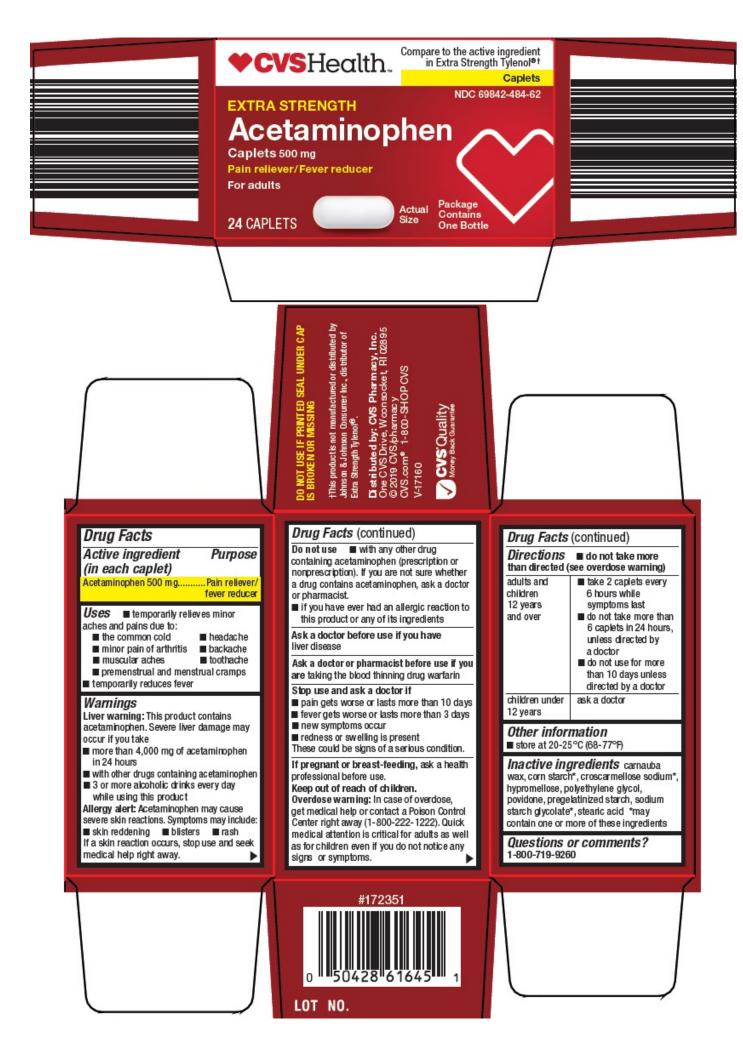
Pain reliever/Fever reducer

For adults

24 CAPLETS

Actual Size

Package Contains One Bottle



## ACETAMINOPHEN

acetaminophen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-484	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
STARCH, CORN (UNII: O8232NY3SJ)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			
PO VIDO NE (UNII: FZ989 GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
CROSCARMELLOSE SODIUM (UNII: M28 O L 1HH48)			

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	16 mm	
Flavor		Imprint Code	L484	
Contains				

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:69842-484-93	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2018		
2	NDC:69842-484-62	1 in 1 CARTON	06/12/2018		
2		24 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:69842-484-71	1 in 1 CARTON	06/12/2018		
3		50 in 1 BOTTLE; Type 0: Not a Combination Product			
4	NDC:69842-484-78	1 in 1 CARTON	06/12/2018		
4		100 in 1 BOTTLE; Type 0: Not a Combination Product			
5	NDC:69842-484-83	1 in 1 CARTON	06/12/2018		
5		225 in 1 BOTTLE; Type 0: Not a Combination Product			

6	NDC:69842-484-90	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2018	
7	NDC:69842-484-87	2 in 1 CARTON	06/12/2018	
7		150 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:69842-484-47	1 in 1 CARTON	06/12/2018	
8		150 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/12/2018	

# Labeler - CVS Pharmacy (062312574)

Revised: 6/2019 CVS Pharmacy