## 8 HR ARTHRITIS PAIN- acetaminophen tablet, film coated, extended release CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

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CVS Pharmacy, Inc. 8 HR Arthritis Pain Drug Facts

#### Active ingredient (in each caplet)

Acetaminophen 650 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

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

#### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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	<ul> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
under 18 years of age	ask a doctor

#### Other information

- store at 20-25°C (68-77°F)
- meets the requirements of USP Dissolution Test 4

#### **Inactive ingredients**

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

# Questions or comments? 1-800-719-9260

#### **Principal Display Panel**

**CVS™** 

actual size

8 HR ARTHRITIS PAIN

Acetaminophen

Extended-Release Tablets USP, 650 mg

Pain Reliever, Fever Reducer

Compare to Tylenol® 8 HR Arthritis Pain active ingredient

For the Temporary Relief of Minor Arthritis Pain

225 CAPLETS, \*650 mg EACH

\*Capsule-Shaped Tablets



#### **8 HR ARTHRITIS PAIN**

acetaminophen tablet, film coated, extended release

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51316-504

**Route of Administration** ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name

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

ACETAMINOPHEN

ACETAMINOPHEN

ACETAMINOPHEN

ACETAMINOPHEN

ACETAMINOPHEN

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics						
Color	WHITE	Score	no score			
Shape	OVAL	Size	19mm			
Flavor		Imprint Code	L544			
Contains						

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:51316-504- 79	400 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2025				
2	NDC:51316-504- 83	225 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2025				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075077	09/29/2025		

## Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Revised: 9/2025

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED