

**CARE ONE ARTHRITIS PAIN RELIEF- acetaminophen tablet, film coated, extended release**  
**American Sales Company**

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**American Sales Company Arthritis Pain Relief 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 style="list-style-type: none"> <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	<ul style="list-style-type: none"> <li>• ask a doctor</li> </ul>

**Other information**

- store at 20-25°C (68-77°F)

- **do not use if printed foil under cap is broken or missing**
- 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**

CAREone®

Compare to the active ingredient in Tylenol® 8HR Arthritis Pain

ARTHRITIS PAIN RELIEF

Acetaminophen Extended-Release Tablets, 650mg

Pain Reliever/Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

Actual Size

225 CAPLETS\*

650mg EACH

\*Capsule-Shaped Tablets



## CARE ONE ARTHRITIS PAIN RELIEF

acetaminophen tablet, film coated, extended release

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:41520-544

**Route of Administration**

ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

## Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
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			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-544-71	1 in 1 CARTON	09/12/2017	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-544-78	1 in 1 CARTON	10/12/2017	01/31/2022
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41520-544-83	1 in 1 CARTON	09/05/2025	
3		225 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	11/22/2005	

