

# **8HR ARTHRITIS PAIN RELIEF- acetaminophen tablet, film coated, extended release**

**CVS Pharmacy**

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## **CVS Pharmacy, Inc. 8HR 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 2

### **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**

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

Caplets†

8HR Arthritis Pain Relief

ACETAMINOPHEN

EXTENDED-RELEASE TABLETS, 650 mg

Pain Reliever/Fever Reducer

For the temporary relief of minor arthritis pain

150 CAPLETS†, 650 mg EACH

†CAPSULE-SHAPED TABLETS

Actual Size

**CVS**Health.

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

Caplets†

NDC 69842-544-47

# 8HR Arthritis Pain Relief

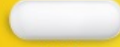
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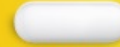
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Actual Size





Caplets<sup>†</sup>

# 8HR Arthritis Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

**Pain Reliever/Fever Reducer**  
For the temporary relief of minor arthritis pain

**150 CAPLETS<sup>†</sup>, 650 mg EACH**  
†CAPSULE-SHAPED TABLETS

U.S. Patent 7,897,172

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Acetaminophen 650 mg.....Pain reliever/fever reducer

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- 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

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- These could be signs of a serious condition.

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## Drug Facts (continued)

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under 18 years of age

- ask a doctor

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

\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Tyleno<sup>®</sup> 8HR Arthritis Pain.

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V-17160



Contains No Aspirin

#346020



0 50728 72108 7



## 8HR ARTHRITIS PAIN RELIEF

acetaminophen tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-544
<b>Route of Administration</b>	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)	
CROSCARMELLOSE 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

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	L544
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69842-544-85	1 in 1 CARTON	04/20/2006	08/31/2021
1		250 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-544-62	1 in 1 CARTON	08/27/2008	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69842-544-47	1 in 1 CARTON	04/20/2006	
3		150 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69842-544-71	1 in 1 CARTON	08/27/2008	07/31/2020
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69842-544-78	1 in 1 CARTON	05/31/2000	10/31/2020
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:69842-544-79	400 in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2018	01/31/2022
7	NDC:69842-544-83	225 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	05/31/2000	

**Labeler** - CVS Pharmacy (062312574)

Revised: 10/2022

CVS Pharmacy