

**ACETAMINOPHEN EXTENDED RELEASE- acetaminophen tablet**  
CVS Pharmacy

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**Drug Facts**

**Active ingredient (in each caplet)**

**Acetaminophen 650 mg**

**Purpose**

**Pain reliever/fever reducer**

**Uses**

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - minor pain of arthritis
  - backache
  - toothache
  - premenstrual and menstrual cramps
  - headache
  - the common cold
- 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 ever 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 a 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 (1800-222-1222) right away. 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**
  - take 2 caplets every 8 hours with water
  - swallow whole; do not crush, chew, split or dissolve
  - do not take more than 6 caplets in 24 hours
  - do not use for more than 10 days unless directed by a doctor
- **children under 12 years of age:** ask a doctor

**Other information**

- store between 20-25°C (68-77°F)

**Inactive ingredients**

D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hydroxyethyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose povidone, pregelatinized starch, sodium lauryl sulfate

**Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Principal Display Panel**

†Compare to the active ingredient of Tylenol® 8HR Muscle Aches & Pain

Extended-release

**Pain Reliever**

Acetaminophen 650 mg

Pain reliever/Fever reducer

For up to 8 hours relief of minor muscle aches & pain

Caplets\*

(\*capsule-shaped bi-layer tablets)

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Muscle Aches & Pain.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

Distributed by: CVS Pharmacy Inc

one CVS Drive, Woonsocket RI 02895

**Product Label**

Exp. Date: \_\_\_\_\_  
Lot No.: \_\_\_\_\_

PLD-A495A FC006789

#199239

0 50428 36904 3



**Drug Facts (continued)**

**Directions** ■ do not take more than directed (see Overdose warning) ■ adults  
■ take 2 caplets every 8 hours with water  
■ swallow whole; do not crush, chew, split or dissolve ■ do not take more than 6 caplets in 24 hours ■ do not use for more than 10 days unless directed by a doctor ■ under 18 years of age: ask a doctor

**Other information**  
■ store between 20-25°C (68-77°F)

**Inactive ingredients** D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hydroxyethyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulfate

**Questions or comments?**  
Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8HR Arthritis Pain.

**Drug Facts (continued)**

**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.**

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**Active ingredient (in each caplet)**  
Acetaminophen 650 mg.....fever reducer

**Purpose**  
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fever reducer

**Uses** ■ temporarily relieves minor aches and pains due to ■ minor pain of arthritis ■ headache ■ the common cold  
■ temporarily reduces fever  
■ backache ■ muscular aches ■ toothache  
■ premenstrual and menstrual cramps  
■ 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.

**CVS Health.** Compare to the active ingredient in Tylenol® 8HR Arthritis Pain\*  
**Caplets†**

NDC 69842-093-24

## 8HR Arthritis Pain Relief

**ACETAMINOPHEN**  
EXTENDED-RELEASE TABLETS, 650 mg

**Pain Reliever/Fever Reducer**

For the temporary relief of minor arthritis pain

Package Contains One Bottle

**24 CAPLETS†, 650 mg EACH**

CAPLET-GUARDED BY-LAYER TABLETS



Actual Size



**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**Distributed by: CVS Pharmacy, Inc.**  
One CVS Drive, Woonsocket, RI 02895  
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V-16402

**CVS Quality**  
Money Back Guarantee

### CVS HEALTH 8HR Arthritis Pain Relief

## ACETAMINOPHEN EXTENDED RELEASE

acetaminophen tablet

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69842-093

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136Y38GY5)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	511
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-093-10	1 in 1 BOX	04/01/2020	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69842-093-24	1 in 1 BOX	04/01/2020	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:69842-093-15	1 in 1 BOX	04/01/2020	
3		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207035	04/01/2020	

**Labeler** - CVS Pharmacy (062312574)

