

## **8HR MUSCLE ACHES AND PAIN RELIEF- acetaminophen tablet, extended release**

**LEADER/ Cardinal Health 110, Inc.**

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### **Cardinal Leader Acetaminophen Extended Release Tablets USP, 650 mg Muscle Aches and Pain**

#### ***Drug Facts***

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#### ***Active ingredient (in each caplet)***

Acetaminophen 650 mg

#### ***Purpose***

Pain reliever/fever reducer

#### ***Uses***

temporarily relieves minor aches and pains due to:

- muscular aches
- backache
- minor pain of arthritis
- 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 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

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adults and children 12 years and over	<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>
children under 12 years	<ul style="list-style-type: none"><li>• do not use</li></ul>

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### ***Other information***

- store between 20-25°C (68-77°F)
- The FDA approved dissolution methods differ from USP

**Inactive ingredients** carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

**Questions or comments?** Call **1-800-632-6900**

# 8HR MUSCLE ACHES AND PAIN RELIEF

NDC 70000-0734-1

## 8HR Muscle Aches & Pain Relief

Acetaminophen Extended-Release Tablets USP, 650 mg

Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches & Pain

100% Money Back Guarantee

100 CAPLETS\*\* 650 mg EACH

(\*\*Capsule-Shaped Bi-Layer Tablets)

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

### Drug Facts

**Active ingredient (in each caplet)**  
Acetaminophen 650 mg

**Uses**

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

**Warnings**

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If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

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children under 12 years: do not use

**Other information** store between 20-25°C (68-77°F) The FDA approved dissolution methods differ from USP

**Questions or comments?** Call 1-877-290-4008

**Contains No Aspirin** DIST. BY CAH, DUBLIN, OH 43007  
www.mylleader.com 1-800-200-6333  
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**CIN 5981915 REV. 04/25**

**LOT:**  
**EXP.:**

**Varnish Omit Area**

C6011AR3

Varnish/Print Omit Area

Varnish Omit Area

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**CIN 5981915 REV. 04/25**

**LOT:**  
**EXP.:**

**Varnish Omit Area**

Cardinal Health  
100% Money Back Guarantee  
This product is not manufactured or distributed by  
Tylenol® Pain Muscle Aches & Pain.  
Cardinal Health  
100% Money Back Guarantee  
This product is not manufactured or distributed by  
Tylenol® Pain Muscle Aches & Pain.

acetaminophen tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0734
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%)</b> (UNII: 8136Y38GY5)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white ((White to off white))	<b>Score</b>	no score
<b>Shape</b>	CAPSULE ((Capsule-shaped tablet))	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	71
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:70000-0734-1	1 in 1 CARTON	06/15/2025	
<b>1</b>		100 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA215486	06/15/2025	

**Labeler** - LEADER/ Cardinal Health 110, Inc. (063997360)

**Registrant** - TIME CAP LABORATORIES, INC (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(70000-0734)

Revised: 6/2025

LEADER/ Cardinal Health 110, Inc.