

**8HR ARTHRITIS PAIN RELIEF- acetaminophen tablet, extended release  
LEADER/ Cardinal Health 110, Inc.**

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**CARDINAL-LEADER Acetaminophen Extended-Release Tablets USP, 650 mg**

***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 n backache
  - premenstrual and menstrual cramps
  - the common cold n 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

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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>

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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 **1-877-290-4008**

LEADER<sup>2</sup>

NDC 70000-0733-2

# 8HR Arthritis Pain Relief

Acetaminophen Extended-Release

Tablets USP, 650 mg

Pain Reliever / Fever Reducer

50 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.....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.

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

**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)  
■ The FDA approved dissolution methods differ from USP

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

**Contains No Aspirin**

**100% Money Back Guarantee**  
Return to place of purchase if not satisfied.

DIST: BY CAH, DUBLIN, OH 43017  
www.yleader.com 1-800-200-6335

Made in India  
CIN 5986179 REV. 05/25 699R

Varnish Omit Area

LOT:  
EXP.:

Varnish/Print Omit Area

LEADER<sup>2</sup>

NDC 70000-0733-2

# 8HR Arthritis Pain Relief

Acetaminophen Extended-Release Tablets USP, 650 mg  
Pain Reliever / Fever Reducer

Lasts up to 8 Hours  
For the Temporary Relief of Minor Arthritis Pain

COMPARE TO  
TYLENOL<sup>®</sup> 8HR  
ARTHRITIS PAIN  
active ingredient\*

100% Money  
Back Guarantee



ACTUAL SIZE

50 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

### Drug Facts

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

### Warnings

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■ 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.

### 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.**

**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.

### Drug Facts (continued)

**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 between 20-25°C (68-77°F)  
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**Inactive ingredients** carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

#### Questions or comments?

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

CIN 5986179 REV. 05/25



LOT:  
EXP.:



# 8HR ARTHRITIS PAIN RELIEF

acetaminophen tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0733
<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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

## 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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0733-1	1 in 1 CARTON	06/15/2025	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0733-2	1 in 1 CARTON	06/21/2025	
2		50 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	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(70000-0733)

Revised: 6/2025

LEADER/ Cardinal Health 110, Inc.