

**ACETAMINOPHEN- acetaminophen tablet
LEADER/ Cardinal Health 110, Inc**

**8HR Arthritis Pain Relief
Acetaminophen Extended-Release Tablets USP 650mg
Pain Reliever/Fever Reducer**

Active ingredient (in each caplet)

Acetaminophen USP, 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

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.

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

- 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)
- **do not use if foil inner seal is broken or missing**

Inactive Ingredients

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

PDP

NDC UNIT DIMENSION	
code #	: CVS 4892 83 1003
code #	:
size	: 2 3/32 X 2 3/32 X 4 3/16
ref #	: PP1806648
material	: 015 585
view	
date	

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 Omaha, NE 68184
 1-800-441-4411
 www.cardinalhealth.com
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COATING FREE AREA

200000004280
700000003286

Important: Read product information before using.
 Carry this caution for important information.
Do not use if foil inner seal is broken or missing.

Drug Facts
Active ingredient (in each caplet) Purpose
 Acetaminophen USP 650 mg Pain Reliever/ Fever Reducer

Uses
 Temporarily relieves minor aches and pains due to:
 ■ minor pain of arthritis
 ■ muscular aches
 ■ headache
 ■ sore throat and sinus pain
 ■ the common cold
 ■ 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
Caution: Acetaminophen may cause severe skin reactions. Symptoms may include:
 ■ skin redness
 ■ 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 over-the-counter) 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

Drug Facts (continued)
 ■ pain symptoms occur
 ■ dizziness or swelling is present
 These could be signs of a serious reaction.
 If pregnant or breastfeeding, 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. (1-800-422-1223)
 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
 ■ 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)
 ■ do not use if foil inner seal is broken or missing

Active ingredients
 hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?
 contact 1-877-470-4183 Mon-Fri 9:00 AM EST to 5:00 PM EST

Contains No Aspirin

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

For the Temporary Relief of Minor Arthritis Pain
100 CAPLETS™ 650 mg EACH
 (Each Caplet is a Shaped 8Hr Layer Tablet)

COMPARE TO TYLENOL® 8 HR ARTHRITIS PAIN active ingredient.*

100% Money Back Guarantee

LEADER?

8HR Arthritis Pain Relief
 Acetaminophen
 Extended-Release Tablets USP 650 mg
 Pain Reliever / Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

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100% Money Back Guarantee

100 CAPLETS™ 650 mg EACH
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COATING FREE AREA

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COATING FREE AREA

Lot

Exp.

CO: 6010079 REV: 1/23

0 76293 14232 3



ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0627
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		Strength
Ingredient Name		
STARCH, CORN (UNII: O8232NY3S)		
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)		
MAGNESIUM STEARATE (UNII: 70097M6130)		
POVIDONE K30 (UNII: U725QWY32X)		

HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0627-1	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	
2	NDC:70000-0627-2	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	
3	NDC:70000-0627-3	225 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	03/23/2023	

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

Revised: 12/2025

LEADER/ Cardinal Health 110, Inc