

ACETAMINOPHEN- acetaminophen tablet
LEADER/ Cardinal Health 110, Inc

8HR Muscle Aches & pain Relief
Acetaminophen Extended-Release Tablets USP, 650mg
Pain reliever/Fever Reducer

Active ingredient (in each caplet)

Acetaminophen USP, 650mg

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

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.

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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 and children 12 years of age 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

- do not use

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

end user :CRANULSS
 item :CVS APAP RR 100CT
 code # :
 size :2+3/32 x 2+3/32 x 4+3/16
 ref # :PP180604A view :2
 material :.016 SRS date :0

COATING FREE AREA
 700000004276
 700000003284

Cardinal Health™
 100% Money Back Guarantee
 Return to date of purchase.
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Important: Read product information before using. Keep the carton 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:
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 headache
 minor pain of arthritis
 toothache
 premenstrual and menstrual cramps
 headache
 the common cold
 temporarily reduces fever

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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

Drug Facts (continued)
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 pain gets worse or lasts more than 10 days
 fever gets worse or lasts more than 3 days
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 Keep out of reach of children.
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Contains No Aspirin
 *This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Muscle Aches & Pain.

For Up to 8 Hours Relief of Minor Muscle Aches & Pain
8HR Muscle Aches & Pain Relief
 Acetaminophen Extended-Release Tablets USP 650 mg Pain Reliever / Fever Reducer
 100 CAPLETS** 650 mg EACH
 (Capsule-Shaped 8H-Layer Tablets)
 Actual Size
 100% Money Back Guarantee
 COMPARE TO TYLENOL® 8 HR MUSCLE ACHEs & PAIN active ingredient*

LEADER?
 NDC 70000-0626-1
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
COMPARE TO TYLENOL® 8 HR MUSCLE ACHEs & PAIN active ingredient*
 100% Money Back Guarantee
 Actual Size
 100 CAPLETS** 650 mg EACH
 (**Capsule-Shaped 8H-Layer Tablets) SEE NEW WARNING!

COATING FREE AREA
 700000004276
 700000003284

COATING FREE AREA
 Lot:
 Exp:
 CN 5816095 REV. 1/23
 0 962954 14253 2

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0626
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

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3S)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white (WHITE TO OFF WHITE COLORED)	Score	no score
Shape	OVAL (CAPSULE SHAPED, BICONVEX INTACT FILM COATED TABLETS)	Size	19mm
Flavor		Imprint Code	G;650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0626-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	03/02/2023	

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

Revised: 12/2023

LEADER/ Cardinal Health 110, Inc