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.

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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

- 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.

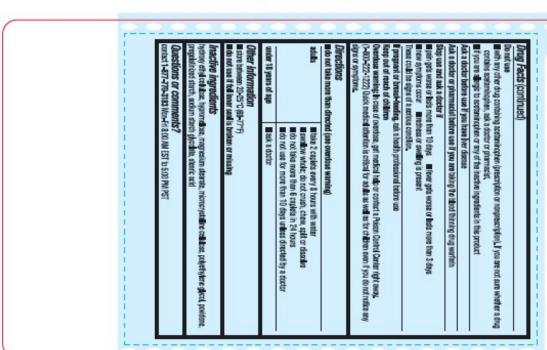
Questions or comments?

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

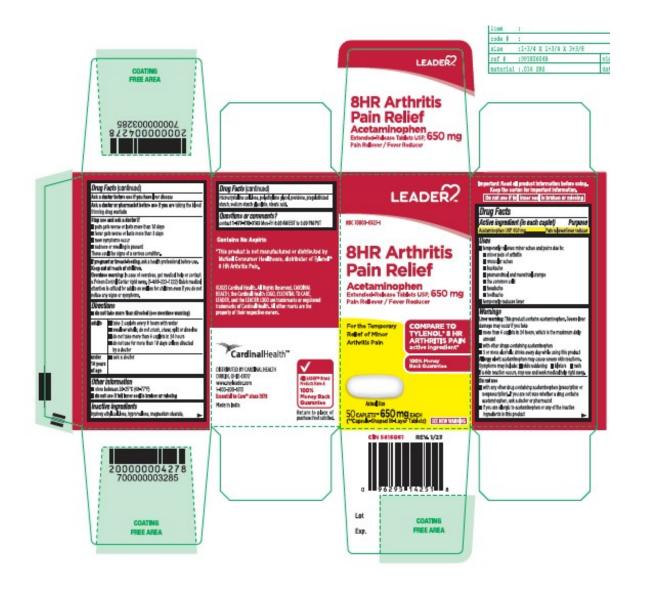
PDP



Inside (adhesive side)







ACETAMINOPHEN

acetaminophen tablet

Product Infor	mation
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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
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ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 650 mg

Inactive	Ingredients

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Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POVIDONE K30 (UNII: U725OWY32X)		

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: 12/2023 LEADER/ Cardinal Health 110, Inc