LEADER 8HR ARTHRITIS PAIN- acetaminophen tablet, film coated, extended release

Cardinal Health 110, LLC. dba Leader

Cardinal Health 8 HR Arthritis Pain 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
- 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.

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)

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 at 20-25°C (68-77°F)
- do not use if printed foil under cap is broken or missing

meets the requirements of USP Dissolution Test 2

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

LEADER™

8HR Arthritis Pain

Acetaminophen Extended-Release Tablets, 650 mg

Pain Reliever / Fever Reducer

COMPARE TO TYLENOL® 8HR ARTHRITIS PAIN active ingredient

For the Temporary Relief of Minor Arthritis Pain

Push & Turn Cap

100 CAPLETS*

650 mg EACH

*Capsule-Shaped Tablets

Actual Size

100% Money Back Guarantee





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- ■the common cold headache ■ toothache
- ■temporarily reduces fever

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Drug Facts (continued)

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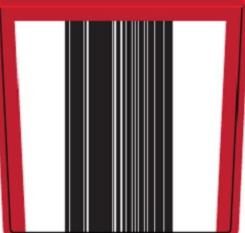
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Questions or comments? 1-800-719-9260

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



acetaminophen tablet, film coated, extended release

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 650 mg

Inactive Ingredients

mactive mgreateries	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L544
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0180-1	250 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2017	11/30/2021
2	NDC:70000- 0180-2	1 in 1 CARTON	02/08/2017	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70000- 0180-3	1 in 1 CARTON	02/08/2017	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70000- 0180-4	1 in 1 CARTON	06/27/2017	06/17/2019

4	120 in 1 BOTTLE; Type 0: Not a Combination Product			
5 NDC:70000- 0180-5	225 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2020		
Marketing Information				
Marketing	Information			
Marketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing	Application Number or Monograph	_	_	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 5/2023 Cardinal Health 110, LLC. dba Leader