

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

**Cardinal Health 110, LLC. dba Leader**

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**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	<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 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

Contains No Aspirin

U.S. Patent 7,897,172



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www.myleader.com 1-800-200-6335  
Essential to Care™ since 1979



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NDC 70000-0180-3



# 8HR Arthritis Pain

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

For the Temporary  
Relief of Minor Arthritis Pain  
Push & Turn Cap

**100 CAPLETS\***  
650 mg EACH \*Capsule-Shaped Tablets



Actual Size

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

100% Money  
Back Guarantee



NDC 70000-0180-3

# 8HR Arthritis Pain

Acetaminophen  
Extended-Release  
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Pain Reliever / Fever Reducer

For the Temporary  
Relief of Minor  
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Push & Turn Cap



Actual Size

**100 CAPLETS\***  
650 mg EACH  
\*Capsule-Shaped Tablets

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

100% Money  
Back Guarantee

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

CIN 5315213

REV. 2/20



0 96295 13131 4

CODE AREA

54478 E9 C4

### Drug Facts

**Active Ingredient (in each caplet) Purpose**  
Acetaminophen 650 mg.....Pain reliever/fever reducer

### Uses

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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

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
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- These could be signs of a serious condition.

### Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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### Directions

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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> |
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- do not use if printed fo il under cap is broken or missing
- meets the requirements of USP Dissolution Test 2

**Inactive ingredients** carnaubawax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, poly sorbate 80, polyvidons, pregelatinized starch, stearic acid, titanium dioxide

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0180
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	L544
<b>Contains</b>			

### 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

<b>4</b>		120 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>5</b>	NDC:70000-0180-5	225 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA075077		01/17/2017	

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

Revised: 5/2023

Cardinal Health 110, LLC. dba Leader