

**LEADER 8 HR MUSCLE ACHES AND PAIN- acetaminophen tablet, film coated, extended release**  
**Cardinal Health 110, LLC. dba Leader**

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**Cardinal Health 8HR Muscle Aches & 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:
- muscular aches
- backache
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- 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 and children 12 years and over	<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>
children under 12 years	<ul style="list-style-type: none"><li>• do not use</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**

### **Package/Label Principal Display Panel**

8HR Muscle Aches & Pain

Acetaminophen Extended-Release Tablets, 650 mg

Pain Reliever / Fever Reducer

For up to 8 Hours Relief of Minor Muscle Aches and Pain

100 CAPLETS\*

650 mg EACH \* Capsule-Shaped Tablets

Actual Size

COMPARE TO TYLENOL® 8HR

active ingredient

100% Money Back Guarantee



Contains No Aspirin  
U.S. Patent 7,997, 172

**CardinalHealth™**  
DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43007  
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**LEADER**

NDC 700 00-0306-1

**8HR Muscle Aches & Pain**  
Acetaminophen Extended-Release Tablets, 650 mg  
Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches and Pain

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

**COMPARE TO TYLENOL® 8HR active ingredient\*\***  
100% Money Back Guarantee

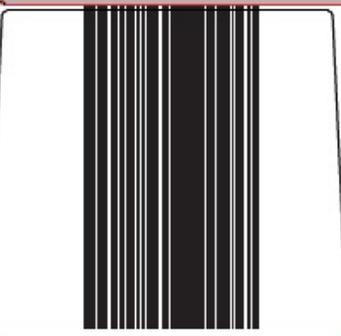
**100% Money Back Guarantee**

**LEADER**

CIN 5331848 REV. 2/20

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551 78 EB C2



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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**

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**Drug Facts (continued)**

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**Other information**

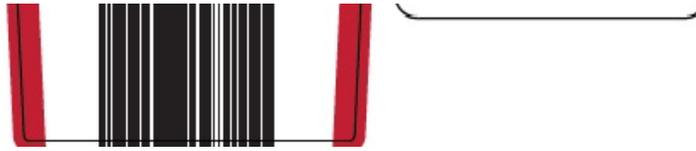
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**Inactive ingredients** carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, polyorbate 80, polydioxane, pregelatinized starch, stearic acid, titanium dioxide

**Questions or comments?** 1-800-719-9260

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





## LEADER 8 HR MUSCLE ACHES AND PAIN

acetaminophen tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0306
<b>Route of Administration</b>	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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

### 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:70000-0306-1	1 in 1 CARTON	05/05/2017	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	05/05/2017	

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

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader