

**ACETAMINOPHEN- acetaminophen tablet  
LEADER/ Cardinal Health 110, Inc**

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**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.**

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 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**



NDC UNIT DIMENSIONAL	
line	: CVS 4892 83 1003
code #	:
size	: 2-3/32 X 2-3/32 X 4-3/16
ref #	: PP180648
material	: 015 585
view	:
date	:

COATING  
FREE AREA

200000004280  
700000003286

Cardinal Health  
8710 E. 16th Avenue  
Denver, CO 80202  
www.cardinalhealth.com  
1-800-521-6278  
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100% Money Back Guarantee  
See back of package for details.

**Important: Read product information before using.**  
Keep this container 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 Reducer / Fever Reducer

**Uses**  
Temporarily relieves minor aches and pains due to:  
■ minor pain of arthritis  
■ muscular aches  
■ headache  
■ sore throat and sinus pain  
■ the common cold  
■ 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.  
**Caution:** Acetaminophen may cause severe skin reactions. Symptoms may include:  
■ skin redness  
■ 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 over-the-counter) 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

**Drug Facts (continued)**  
■ pain symptoms occur  
■ dizziness or swelling is present  
These could be signs of a serious reaction.  
■ pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.  
**Overuse warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-422-4225)  
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  
children 12 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

**Active ingredients:**  
hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

**Questions or comments?**  
contact 1-877-470-4183 Mon-Fri 9:00 AM EST to 5:00 PM EST

Contains No Aspirin

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

100% MONEY BACK GUARANTEE  
See back of package for details.

For the Temporary Relief of Minor Arthritis Pain  
**100 CAPLETS™ 650 mg EACH**  
Acetaminophen Extended-Release Tablets USP 650 mg  
Pain Reducer / Fever Reducer

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

100% Money Back Guarantee

**LEADER?**

8HR Arthritis Pain Relief  
Acetaminophen  
Extended-Release Tablets USP 650 mg  
Pain Reducer / Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

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

100% Money Back Guarantee

100 CAPLETS™ 650 mg EACH  
(\*Capsule-Shaped 8Hr Layer Tablets)

COATING  
FREE AREA

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COATING  
FREE AREA

Lot

Exp.

CO: 6816079 REV: 1/23

0 76293 14232 3



## ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0627
<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>STARCH, CORN</b> (UNII: O8232NY3S)	
<b>HYDROXYETHYL CELLULOSE (140 CPS AT 5%)</b> (UNII: 8136Y38GY5)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	

<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	G650
<b>Contains</b>			

### 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