

# **LEADER EXTRA STRENGTH ACETAMINOPHEN- acetaminophen capsule, liquid filled**

**Cardinal Health**

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## **Leader™ Extra Strength Acetaminophen**

### **Drug Facts**

#### **Active ingredient (in each softgel)**

Acetaminophen 500 mg

#### **Purpose**

Pain reliever/ fever reducer

#### **Uses**

- temporarily relieves minor aches and pains due to:
- the common cold ■ headache ■ backache
- minor pain of arthritis ■ toothache ■ muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

#### **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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.

- 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**)

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Adults and children 12 years and over	<ul style="list-style-type: none"><li>■ take 2 softgels every 6 hours while symptoms last</li><li>■ do not take more than 6 softgels in 24 hours unless directed by a doctor</li><li>■ do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	ask a doctor

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### Other information

- **each softgel contains:** sodium 7 mg
- store between 15°-30°C (59°-86°F)

### Inactive ingredients

FD&C Red #40, gelatin, glycerin, polyethylene glycol 400, potassium hydroxide, povidone, propylene glycol, purified water, sodium hydroxide, sorbitol, sorbitol sorbitan solution titanium dioxide

**Questions or Comments? 1-888-333-9792**

### PRINCIPAL DISPLAY PANEL

**Leader™ Extra Strength Acetaminophen**

Compare to the active ingredient

in Tylenol® Extra Strength\*  
Liquid-Filled Capsules\*\*

**EXTRA STRENGTH**

Acetaminophen USP 500mg

Pain Reliever; Fever reducer

Aspirin free

40 SOFTGELS\*\*

\*\*Liquid filled capsules

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY  
SEAL UNDER CAP IS BROKEN OR MISSING

This product is not manufactured  
or distributed by McNeil Consumer  
Healthcare, owner of the  
registered trademark Tylenol®  
Extra Strength.

Distributed by: CARDINAL HEALTH  
DUBLIN, OHIO 43017  
Made in India  
CIN 5546221

**LEADER<sup>2</sup>**

NDC 70000-0509-1  
**Extra Strength Acetaminophen**  
 Softgels, 500 mg  
 Pain Reliever / Fever Reducer

**FOR ADULTS**  
Aspirin-Free

**COMPARE TO TYLENOL<sup>®</sup> EXTRA STRENGTH**  
active ingredient\*

100% Money Back Guarantee

**40 SOFTGELS\*\***  
(\*\*Liquid-Filled Capsules)

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**  
**Active ingredient (in each softgel)** Purpose  
 Acetaminophen 500 mg .....Pain reliever/ fever reducer

**Uses**  
 ■ temporarily relieves minor aches and pains due to:  
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 ■ more than 4,000 mg of acetaminophen in 24 hours  
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**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.

**Drug Facts (continued under label)**

DISTRIBUTED BY CARDINAL HEALTH  
 DUBLIN, OHIO 43007  
 \*Made in India  
 © 2019 Cardinal Health  
 \*This product is not mandated used or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol<sup>®</sup> Extra Strength.

**100% Money Back Guarantee**  
 Return to place of purchase.  
 CIN 5546221 REV. 8/19  
 FPO  
 96295113819 1

LOT: \_\_\_\_\_  
 EXP: \_\_\_\_\_

SEE HERE

**Drug Facts (continued)**

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**  
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 ■ new symptoms occur  
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 adults and children  
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**Other information**  
 ■ each softgel contains sodium 7 mg  
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**Inactive ingredients**  
 FD&C Red #40, gelatin, glycerin, polyethylene glycol 400, potassium hydroxide, polydioxane, propylene glycol, purified water, sodium hydroxide, sorbitol, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?** 1-888-333-9792

## LEADER EXTRA STRENGTH ACETAMINOPHEN

acetaminophen capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0509
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	

<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red (transparent)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	23mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	710
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0509-1	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/10/2019	

**Labeler** - Cardinal Health (063997360)