

**ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, film coated**  
**CVS Pharmacy**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Pain Reliever**

***Active ingredient (in each caplet)***

Acetaminophen 500 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - headache
  - backache
  - the common cold
  - toothache
  - minor pain of arthritis
  - 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:

- rash
- skin reddening
- blisters

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**

- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur

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.**

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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**
- adults and children 12 years and over
  - take 2 caplets every 6 hours while symptoms last
  - do not take more than 6 caplets in 24 hours, unless directed by a doctor
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

***Inactive ingredients***

castor oil, hypromellose, povidone, sodium starch glycolate, starch, stearic acid

***Questions or comments?***

**1-800-426-9391**

***Principal Display Panel***

**TWIN PACK 2 x 10 COUNT VIALS**

♥ **CVS**  
**Health™**

Compare to the active ingredient  
in Extra Strength Tylenol®\*

**Caplets**

**EXTRA STRENGTH**  
**ACETAMINOPHEN**  
Caplets, 500 mg

Pain reliever, Fever reducer

**TAMPER EVIDENT:**  
Use Only if This Blister is Intact

**Actual Size**

**20 CAPLETS (2 VIALS - 10 CAPLETS EACH)**

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol®.  
REV0617A17503

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Money Back Guarantee

**TWIN PACK** **2 x 10 COUNT VIALS**

**CVS Health.** Compare to the active ingredient in Extra Strength Tylenol®  
Caplets

**EXTRA STRENGTH**  
**Acetaminophen**  
Caplets, 500 mg  
Pain reliever, Fever reducer

**TAMPER EVIDENT:**  
Use Only if This Blister is Intact

Actual Size

**20 CAPLETS (2 VIALS - 10 CAPLETS EACH)**

No Varnish / Copy Free Area

No Print / No Varnish Area  
Lot & Exp. Area

**RETAIN VIAL CARD FOR COMPLETE PRODUCT INFORMATION**

<b>Drug Facts</b> <b>Active ingredient (in each caplet) Purpose</b> Acetaminophen 500 mg .....Pain reliever/fever reducer	<b>Drug Facts (continued)</b> Stop use and ask a doctor if ■ redness or swelling is present ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur 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. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
<b>Uses</b> temporarily relieves minor aches and pains due to: ■ muscular aches ■ headache ■ backache ■ the common cold ■ toothache ■ minor pain of arthritis ■ premenstrual and menstrual cramps ■ temporarily reduces fever	<b>Directions</b> ■ do not take more than directed ■ adults and children 12 years and over ■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not take for more than 10 days unless directed by a doctor ■ children under 12 years: ask a doctor
<b>Warnings</b> <b>Liver warning:</b> 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 <b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ rash ■ skin reddening ■ blisters If a skin reaction occurs, stop use and seek medical help right away. <b>Do not use</b> ■ 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 <b>Ask a doctor before use if you have liver disease.</b> <b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b>	<b>Other information</b> ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package <b>Inactive ingredients</b> castor oil, hypromellose, povidone, sodium starch glycolate, starch, stearic acid <b>Questions or comments?</b> 1-800-426-9391

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Money Back Guarantee

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# ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-750
Route of Administration	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
CASTOR OIL (UNII: D5340Y2I9G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;175
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-750-03	1 in 1 PACKAGE	04/02/1993	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-750-96	2 in 1 PACKAGE	04/02/1993	
2		10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/02/1993	

**Labeler** - CVS Pharmacy (062312574)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	MANUFACTURE(69842-750) , PACK(69842-750)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(69842-750)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	PACK(69842-750)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	PACK(69842-750)

Revised: 9/2019

CVS Pharmacy