

**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet**  
**P & L Development, LLC**

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**Drug Facts**

**Active ingredient (in each caplet)**

**Acetaminophen 500 mg**

**Purpose**

**Pain reliever/fever reducer**

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - 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 ever 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 a 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. 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
  - take 2 caplets every 6 hours while symptoms last
  - do not take more than 6 caplets in 24 hours
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use

## **Other information**

- store between 20-25°C (68-77°F)

## **Inactive ingredients**

corn starch, croscarmellose sodium\*, hypromellose\*, lactose monohydrate\*, magnesium stearate\*, maltodextrin\*, medium-chain triglycerides\*, mineral oil\*, polydextrose\*, polyethylene glycol\*, polyvinyl alcohol\*, povidone, purified water\*, sodium starch glycolate, stearic acid\*, talc\*, titanium dioxide

\*contains one or more of these ingredients

## **Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

## **Principal Display Panel**

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

Extra Strength

### **Pain Reliever**

**Acetaminophen, 500 mg**

Pain Reliever/Fever Reducer

Caplets

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

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

**Distributed by:**

**PL Developments**

**200 Hicks Street**

**Westbury, NY 11590**

**Product Label**

Exp. Date:

Lot No.:

PLD-A108D FC008016



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PL Developments  
200 Hicks Street  
Westbury, NY 11590

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- 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.

### Drug Facts (continued)

- 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.

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#### Questions or comments? Call

1-877-753-3835 Monday-Friday 9AM-5PM EST

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**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**



†Compare to the active ingredient in Tylenol® Extra Strength NDC 59726-494-50

# extra strength pain reliever

## Acetaminophen 500 mg

pain reliever/fever reducer

### 50 caplets



actual size

### READYinCASE Pain Reliever

# PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-494
<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	500 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL341;AV;0821;P500
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-494-24	1 in 1 BOX	03/31/2016	

1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-494-05	1 in 1 BOX	03/31/2016	
2		500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59726-494-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	
4	NDC:59726-494-50	1 in 1 BOX	03/31/2016	
4		50 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 Drug	M013	03/31/2016	

**Labeler** - P & L Development, LLC (800014821)

Revised: 4/2024

P & L Development, LLC