

## **EXTRA STRENGTH PAIN RELIEVER- acetaminophen tablets 500 mg tablet WALGREENS**

*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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**342R Walgreens 0363 0684 Acetaminophen 500 mg 50s**

### **DRUG FACTS**

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

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 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 using 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 (1-800-222-1222) 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 tablets every 6 hours while symptoms last
- do not take more than 6 tablets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

**children under 12 years:** ask a doctor

## **OTHER INFORMATION**

***Other information***

- store between 20-25°C (68-77°F)

***Inactive ingredients*** carnauba wax, FD&C Red #40 aluminum lake, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid, sucralose, titanium dioxide \*may contain this ingredient

***Questions and comments?Call 1-877-290-4008***

NDC 0363-0684-05

**Walgreens**

# Pain Reliever

ACETAMINOPHEN 500 mg / PAIN RELIEVER / FEVER REDUCER

Extra Strength  
• Easy to swallow

**50** COATED TABLETS

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**

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

**Warnings** (See carton for complete warnings information)  
**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

**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 (1-800-222-1222) 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 tablets every 6 hours while symptoms last ■ do not take more than 6 tablets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor  
**children under 12 years:** ■ ask a doctor

**Other information** ■ **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**  
 ■ store between 20-25°C (68-77°F)

**Questions and comments? Call 1-877-290-4008**  
 Walgreens Pharmacist Recommended.  
 Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.  
 DISTRIBUTED BY: WALGREEN CO.  
 200 WILMOT RD., DEERFIELD, IL 60015  
**100% SATISFACTION GUARANTEED**  
 walgreens.com ©2021 Walgreen Co. 342R 0821

Varnish  
Omit Area

Lot No.:  
Exp. Date:

READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE BOX FOR IMPORTANT INFORMATION.

**Drug Facts**

**Active ingredient (in each tablet)**

Acetaminophen 500 mg . . . . . 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:

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- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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- skin reddening ■ blisters ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

**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 using and ask a doctor if**

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- 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 (1-800-222-1222) 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** (continued)

do not take more than directed (see overdose warning)

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**children under 12 years** ask a doctor

**Other information**

- store between 20-25°C (68-77°F)

**Inactive ingredients** carnauba wax, FD&C Red #40 aluminum lake, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid, sucralose, titanium dioxide  
 \*may contain this ingredient

**Questions and comments?**  
 Call 1-877-290-4008

**Walgreens**  
 Compare to the active ingredient in Extra Strength Tylenol®.

**Pain Reliever**  
 ACETAMINOPHEN 500 mg / PAIN RELIEVER / FEVER REDUCER

Extra Strength • Easy to swallow

**50** COATED TABLETS

ACTUAL SIZE

Compare to the active ingredient in Extra Strength Tylenol®.

Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.  
 \*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Tylenol®.

342R 0821

PAPER BOX    PLASTIC BOTTLE

LOT NO.    EXP. DATE

**EXTRA STRENGTH PAIN RELIEVER**

acetaminophen tablets 500 mg tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0684
<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>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL342
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0684-05	1 in 1 CARTON	10/13/2021	
1		50 in 1 BOTTLE; 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	10/13/2021	

**Labeler** - WALGREENS (008965063)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(0363-0684)

Revised: 12/2021

WALGREENS