

ACETAMINOPHEN- acetaminophen 500mg tablet, film coated
CVS Pharmacy, Inc.

342R- CVS Acetaminophen 500mg Tablets

Drug Facts

Active ingredient (in each tablet)

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

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 (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 and children 12 years and over | <ul style="list-style-type: none"> • 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

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

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 or comments? Call **1-877-290-4008**

Adhesive Area

Drug Facts (continued)

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

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Questions or comments?
Call 1-877-290-4088



actual size

Extra Strength ACETAMINOPHEN

Pain Reliever, Fever Reducer, 500 mg

Compare to Tylenol® Extra Strength active ingredient†

150 FILM COATED TABLETS

Contains No Aspirin

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

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Drug Facts (continued under label)

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., Medical Consumer Healthcare Division, owner of the registered trademark Tylenol® Extra Strength.

Distributed by:
CVS Pharmacy, Inc.
Woonsocket, RI 02895
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CVS.com
1-800-SHOP-CVS
342R 0125

FPO 80%
UPC# 050428163993

LOT:
EXP:

Varnish Omit Area



actual size

Extra Strength ACETAMINOPHEN

Pain Reliever, Fever Reducer, 500 mg

Compare to Tylenol® Extra Strength active ingredient†

300 FILM COATED TABLETS

Contains No Aspirin

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CVS.com
1-800-SHOP-CVS
342R 0125

FPO 70%
UPC# 050428164204

LOT:
EXP:

Varnish Omit Area

ACETAMINOPHEN

acetaminophen 500mg tablet, film coated

Product Information

| | | | | | |
|--|------------------|--|----------------------|--------------------|---------------|
| Product Type | | HUMAN OTC DRUG | Item Code (Source) | | NDC:51316-342 |
| 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 | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | | | |
| FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T) | | | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | | | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | | | | | |
| | | | | | |
| Product Characteristics | | | | | |
| Color | | red | Score | no score | |
| Shape | | ROUND | Size | 11mm | |
| Flavor | | | Imprint Code | TCL342 | |
| Contains | | | | | |
| | | | | | |
| Packaging | | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:51316-342-74 | 150 in 1 BOTTLE; Type 0: Not a Combination Product | 05/10/2025 | | |
| 2 | NDC:51316-342-32 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 05/10/2025 | | |
| | | | | | |
| Marketing Information | | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | | M013 | 05/10/2025 | | |

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

| Establishment | | | |
|---------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| TIME CAP LABORATORIES INC | | 037052099 | manufacture(51316-342) |

Revised: 4/2025

CVS Pharmacy, Inc.