

ACETAMINOPHEN- acetaminophen tablet

Pharmacy Value Alliance, LLC

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.

Extra Strength

Pain Reliever

Acetaminophen Tablets, USP 500 mg (Caplets)

PAIN RELIEVER/FEVER REDUCER

DYE-FREE

For Adults

Active ingredient

(in each Caplet)

Acetaminophen, USP 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 the 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 caplets every 6 hours while symptoms last
- do not take more than 6 caplets 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

- store between 20-25°C (68-77°F). See USP Controlled Room Temperature
- see end panel for lot number and expiration date

Inactive ingredients

hydroxypropyl methyl cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST.

JOB INFORMATION

CUSTOMER: GRANULES
MASTER #: J71176AM
EPF #: 891987
DIMENSIONS: 1.5625 x 1.5625 x 3

JOB HISTORY

Original: DA
Rev #1: XXX
Rev #2: XXX
Rev #3: XXX

COLORS USED:

Coating: Cyan
Coating Free: Magenta
Coating Free: Yellow
Coating Free: Black

ATTENTION:
 All content in DIELINE color does not print. This includes center marks.

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Job Information: CUSTOMER: GRANULES, MASTER #: J71176AM, EPF #: 891987, DIMENSIONS: 1.5625 x 1.5625 x 3. JOB HISTORY: Original: DA, Rev #1: XXX, Rev #2: XXX, Rev #3: XXX. COLORS USED: Coating: Cyan, Coating Free: Magenta, Coating Free: Yellow, Coating Free: Black.

Product Label: Premier Value Extra Strength Pain Reliever Acetaminophen Tablets, USP 500 mg. PAIN RELIEVER/FEVER REDUCER. DYE-FREE • For Adults. 24 Capslets - 500 mg each (1 Capsule-Shaped Tablet).

Drug Facts (continued): Do not use if you are allergic to acetaminophen or any of its ingredients. Ask a doctor before use if you have liver disease. Take as directed. Do not take more than 6 capsules in 24 hours. Do not use for more than 10 days unless directed by a doctor. **Warnings:** Do not take if you are pregnant or breastfeeding. Do not take if you are taking other drugs containing acetaminophen. **Questions or Comments?** Call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST.

Coating Free Area: COATING FREE AREA. Lot: Exp.

Barcode: 8 40986 03187 8. 31 80000 980. MADE IN INDIA.

Front Top

Premier Value
Extra Strength Pain Reliever
 Acetaminophen Tablets, USP 500 mg
PAIN RELIEVER/FEVER REDUCER
 DYE-FREE • For Adults

† 500 Caplets - 500 mg each
 (†Capsule-Shaped Tablets)

Drug Facts
Active Ingredient (in each caplet)
 Acetaminophen USP 500 mg

Purpose
 Pain reliever / fever reducer.

Uses
 Acetaminophen USP 500 mg relieves minor aches and pains due to:
 ■ the common cold
 ■ headache
 ■ muscle pain or arthritis
 ■ toothache
 ■ menstrual cramps
 ■ temporary reduces fever

Warnings
 This product contains acetaminophen. Severe liver damage may occur if you take:
 ■ more than 4,000 mg of acetaminophen in 24 hours
 ■ with other drug containing acetaminophen
 ■ if you take more than the recommended dose of this product
 Always take acetaminophen only as directed. Symptoms may include:
 ■ skin rash/itching
 ■ blisters
 ■ hives
 ■ 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 taking the blood thinning drug warfarin.

Ask a doctor or pharmacist before use if you have liver disease
Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Directions
 Pain pills worse or lasts more than 10 days
 ■ fever pills worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ rash or hives appear
 ■ pregnant or breast-feeding, ask a health professional before use.

Other information
 ■ This product is not intended for use by children under 12 years of age.
 ■ Data Strength 1112676, Caplets.

MADE IN INDIA
ASPIRIN FREE
GLUTEN FREE

Lot _____
Exp. _____

Barcode: 8 40986 03189 2

FOLD PROOF ALONG DOTTED LINE to simulate an actual printed label layout

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Drug Facts (continued)
Directions
 Do not take more than directed (see overdose warning)
 ■ do not take more than 2 capsules every 6 hours while symptoms last
 ■ do not take more than 10 capsules in 24 hours, unless directed by a doctor
 ■ do not use for more than 10 days unless directed by a doctor

Other information
 ■ children under 12 years
 ■ adults and children 12 years
 ■ See and panel for lot number and expiration date

Inactive ingredients
 hydroxypropyl methylcellulose, polyethylene glycol, polydextrose starch, sodium starch glycolate, stearic acid.

Questions or comments? Call 1-877-776-3183 Mon-Fri 9:00 AM to 4:30 PM EST

| | | | |
|---|--|--|---|
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ACETAMINOPHEN

acetaminophen tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68016-650 |
| 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 |
|--|----------|
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| POVIDONE (UNII: FZ989GH94E) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | | Imprint Code | G551 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68016-650-24 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 02/25/2016 | |
| 2 | NDC:68016-650-05 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 02/25/2016 | |
| 3 | NDC:68016-650-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 02/25/2016 | |
| 4 | NDC:68016-650-50 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 02/25/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 02/25/2016 | |

Labeler - Pharmacy Value Alliance, LLC (101668460)

Revised: 12/2020

Pharmacy Value Alliance, LLC