

## **ACETAMINOPHEN- acetaminophen tablet, coated UNFI**

*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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**1092-ELN-2022-0915**

### **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"><li>▪ take 2 tablets every 6 hours while symptoms last</li><li>▪ swallow whole – do not crush, chew, or dissolve</li><li>▪ do not take more than 6 tablets in 24 hours, unless directed by a doctor</li><li>▪ do not use for more than 10 days unless directed by a doctor</li></ul> |
| children under 12 years               | <ul style="list-style-type: none"><li>▪ ask a doctor</li></ul>   |

**Other information**

- store between 20-25°C (68-77°F)
- retain carton for complete product information

### **Inactive ingredients**

acesulfame potassium, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

### **Questions or comments?**

1-855-423-2630

### **PRINCIPAL DISPLAY PANEL**

EQUALINE®

NDC 41163-592-01

compare to Extra Strength Tylenol® Coated Tablets active ingredient\*

extra strength

acetaminophen coated tablets

pain reliever/fever reducer

for adults

sweet coated

100 tablets - 500 mg each

actual size



## ACETAMINOPHEN

acetaminophen tablet, coated

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:41163-592 |
| <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>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)                |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                 |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)                      |
| <b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)               |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                       |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)    |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                      |
| <b>POVIDONE</b> (UNII: FZ989GH94E)                            |
| <b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3S)          |
| <b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B) |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                        |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                    |

### 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> | A92      |
| <b>Contains</b> |       |                     |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:41163-592-01 | 1 in 1 CARTON   | 09/15/2022           |                    |
| 1 |                  | 100 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                                  | 09/15/2022           |                    |

**Labeler** - UNFI (006961411)