**PAIN RELIEF- acetaminophen tablet, coated**
**CHAIN DRUG CONSORTIUM**

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**1098-PRV-2020-0823**

***Drug Facts***

## Active ingredient (in each caplet)

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 | ▪ take 2 caplets every 6 hours while symptoms last<br>▪ swallow whole – do not crush, chew, or dissolve<br>▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor<br>▪ 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)
- retain carton for complete product information

**Inactive ingredients**

acesulfame potassium, flavor, hypromellose, polyethylene glycol, povidone,

pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**

1-844-705-4384

**PRINCIPAL DISPLAY PANEL**

Premier Value®

COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® EXTRA STRENGTH COOL CAPLETS†

EXTRA STRENGTH

Pain Relief

FOR ADULTS

ACETAMINOPHEN • COOL CAPLETS

PAIN RELIEVER/FEVER REDUCER

Instant Cooling Sensation

50 CAPLETS, 500 MG EACH


# PAIN RELIEF

acetaminophen tablet, coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68016-503 |
| **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** |
| **ACESULFAME POTASSIUM** (UNII: 23OV73Q5G9) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **STARCH, PREGELATINIZED CORN** (UNII: O8232NY3SJ) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | MINT | **Imprint Code** | AAA;1098 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:68016-503-02 | 1 in 1 CARTON | 05/01/2011 | 06/30/2024 |
| **1** | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:68016-503-03 | 1 in 1 CARTON | 05/01/2011 | 06/30/2024 |
| **2** | | 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 Drug | M013 | 05/01/2011 | 06/30/2024 |

**Labeler -** CHAIN DRUG CONSORTIUM (101668460)

Revised: 10/2023 CHAIN DRUG CONSORTIUM