**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated**
**CHAIN DRUG MARKETING ASSOCIATION, INC.**

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**1004-QCH-2024-0613**

***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>▪ 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**

hypromellose, mineral oil, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

**PRINCIPAL DISPLAY PANEL**

Quality Choice®

NDC 83324-078-01

†Compare to Active Ingredient in TYLENOL® Extra Strength Caplets

For Adults

Extra Strength

Pain Relief

Acetaminophen

Pain Reliever | Fever Reducer

100 CAPLETS - 500 MG EACH


**PAIN RELIEF EXTRA STRENGTH**

acetaminophen tablet, coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:83324-078 |
| **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 |
|---|---|
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **STARCH, PREGELATINIZED CORN** (UNII: O8232NY3SJ) | |
| **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** | | **Imprint Code** | M2A4;57344 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:83324-078-24 | 1 in 1 CARTON | 04/03/2024 | |
| **1** | | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:83324-078-50 | 1 in 1 CARTON | 04/03/2024 | |
| **2** | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **3** | NDC:83324-078-01 | 1 in 1 CARTON | 04/03/2024 | |
| **3** | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **4** | NDC:83324-078-15 | 150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/03/2024 | |
| **5** | NDC:83324- | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a | 04/03/2024 | |

| | | | | |
|---|---|---|---|---|
| 3 | 078-05 | Combination Product | 04/03/2024 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M013 | 04/03/2024 | |

## Labeler - CHAIN DRUG MARKETING ASSOCIATION, INC. (011920774)

Revised: 12/2025 CHAIN DRUG MARKETING ASSOCIATION, INC.