**ARTHRITIS PAIN RELIEF- acetaminophen tablet, extended release**
**TOPCO ASSOCIATES LLC**

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**1200A-TCR-2022-1004**

***Drug Facts***

## Active ingredient (in each caplet)

Acetaminophen 650 mg

## Purpose

Pain reliever/fever reducer

## Uses

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever

## Warnings

### Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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 | ▪ take 2 caplets every 8 hours with water<br>▪ swallow whole; do not crush, chew, split 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 |
| under 18 years of age | ▪ ask a doctor |

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

**Inactive ingredients**

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose,

polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**PRINCIPAL DISPLAY PANEL**

TopCare® health

NDC 36800-632-02

COMPARE TO TYLENOL® 8HR ARTHRITIS PAIN ACTIVE INGREDIENT*

Arthritis Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

PAIN RELIEVER • FEVER REDUCER

For the Temporary Relief of Minor Arthritis Pain

8 HOUR

actual size

50 CAPLETS** - 650 mg EACH ** CAPSULE SHAPED BI-LAYER TABLETS


# ARTHRITIS PAIN RELIEF

acetaminophen tablet, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:36800-632 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%)** (UNII: 8136Y38GY5) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **POVIDONE K30** (UNII: U725QWY32X) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | G650 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:36800-632-01 | 1 in 1 CARTON | 10/04/2022 | |
| **1** | | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:36800-632-02 | 1 in 1 CARTON | 10/04/2022 | |
| **2** | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **3** | NDC:36800-632-03 | 1 in 1 CARTON | 10/04/2022 | |
| **3** | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **4** | NDC:36800-632-05 | 150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/04/2022 | |

# Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA211544 | 10/04/2022 | |

**Labeler -** TOPCO ASSOCIATES LLC (006935977)

Revised: 10/2022 TOPCO ASSOCIATES LLC