# PAIN RELIEVER RAPID RELEASE- acetaminophen tablet, coated Strategic Sourcing Services LLC

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SMK - 1170 - 2022-0922

**Drug Facts** 

## Active ingredient (in each gelcap)

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<br>children 12<br>years and over | <ul> <li>take 2 gelcaps every 6 hours while symptoms last</li> <li>do not take more than 6 gelcaps 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<br>12 years                  | ask a doctor   |

#### Other information

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

# Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone,

pregelatinized starch, stearic acid, titanium dioxide

#### **Questions or comments?**

Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

#### PRINCIPAL DISPLAY PANEL

sunmark®

COMPARE TO TYLENOL® RAPID RELEASE GELS ACTIVE INGREDIENT†

NDC 49348-116-10

Extra Strength

For Adults

pain relief

**ACETAMINOPHEN** 

Pain reliever & Fever reducer

**ACTUAL SIZE** 

100 GELCAPS - 500 MG EACH



# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-116 Route of Administration ORAL

| Active Ingredient/Active Moiety                                    |                          |          |  |
|--|--------------------------|----------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN            | 500 mg   |  |

| Inactive Ingredients                                    |          |
|---|----------|
| Ingredient Name   | Strength |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                      |          |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)                |          |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)                       |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                      |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                      |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                    |          |
| GELATIN (UNII: 2G86QN327L)                              |          |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) |          |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)            |          |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357)                  |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                     |          |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT)                  |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)     |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)                |          |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)          |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                         |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                     |          |
|   |          |

| Product Characteristics |                                |              |          |
|-------------------------|--------------------------------|--------------|----------|
| Color                   | gray (red and light blue ends) | Score        | no score |
| Shape                   | OVAL                           | Size         | 19mm     |
| Flavor                  |                                | Imprint Code | G1       |
| Contains                |                                |              |          |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |
|           | NDC:49348-<br>116-10 | 1 in 1 CARTON   | 10/24/2014              | 03/31/2025            |
| 1         |                      | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M013  | 10/24/2014              | 03/31/2025            |
|                       |   |                         |                       |

# Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 10/2023 Strategic Sourcing Services LLC