**TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated**
**Kenvue Brands LLC**

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## Tylenol ® Extra Strength

***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)
- **do not use if carton is opened. Do not use if foil inner seal imprinted with "TYLENOL" is broken or missing**

**Inactive ingredients**

carnauba wax [1], corn starch [1], FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, modified starch [1], polyethylene glycol [1], powdered cellulose,

pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

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1 contains one or more of these ingredients

**Questions or comments?**

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

**PRINCIPAL DISPLAY PANEL**

NDC 50580-937-07

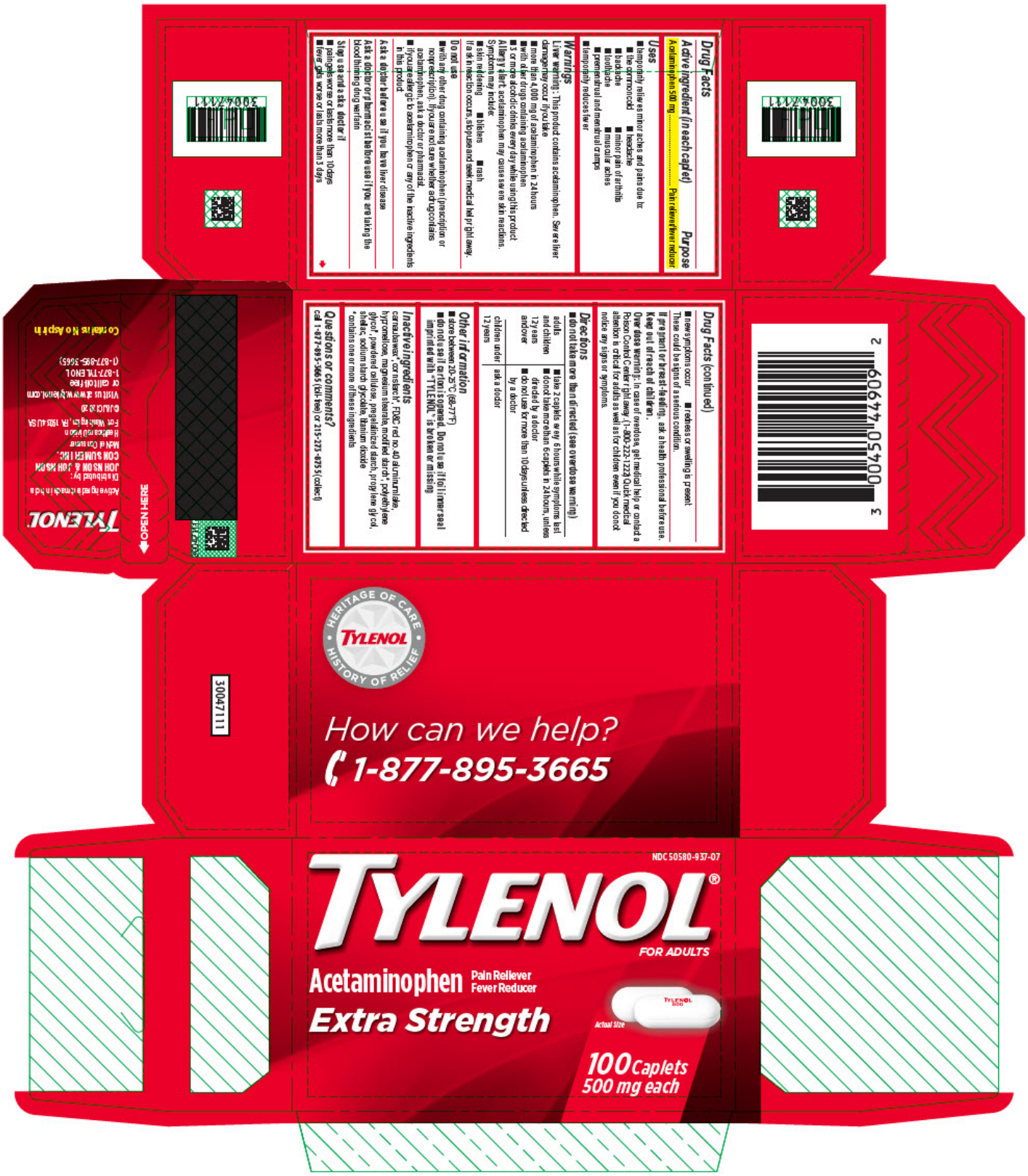
TYLENOL ®
FOR ADULTS

Acetaminophen
Pain Reliever
Fever Reducer

Extra Strength

Actual Size

100 Caplets
500 mg each




# TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50580-937 |

| | |
|---|---|
| **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 |
|---|---|
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POWDERED CELLULOSE** (UNII: SMD1X3XO9M) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white (RED PRINT) | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | TYLENOL;500 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:50580-937-01 | 12 in 1 PACKAGE | 08/19/2019 | |
| **1** | | 10 in 1 VIAL; Type 0: Not a Combination Product | | |
| **2** | NDC:50580-937-02 | 12 in 1 PACKAGE | 09/16/2019 | |
| **2** | | 10 in 1 VIAL; Type 0: Not a Combination Product | | |
| **3** | NDC:50580-937-03 | 2 in 1 POUCH; Type 0: Not a Combination Product | 07/31/2020 | 10/31/2022 |
| **4** | NDC:50580-937-04 | 3 in 1 CARTON | 07/31/2020 | 11/08/2022 |
| **4** | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| **5** | NDC:50580-937-05 | 50 in 1 CARTON | 07/31/2020 | 10/31/2022 |
| **5** | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |

| | | | | |
|---|---|---|---|---|
| **6** | NDC:50580-937-20 | 50 in 1 CARTON | 07/31/2020 | 10/31/2022 |
| **6** | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| **7** | NDC:50580-937-06 | 1 in 1 CARTON | 08/31/2020 | |
| **7** | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **8** | NDC:50580-937-10 | 1 in 1 CARTON | 08/31/2020 | |
| **8** | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **9** | NDC:50580-937-07 | 1 in 1 CARTON | 08/31/2020 | |
| **9** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **10** | NDC:50580-937-15 | 1 in 1 CARTON | 08/31/2020 | |
| **10** | | 225 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **11** | NDC:50580-937-19 | 325 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2020 | |
| **12** | NDC:50580-937-66 | 2 in 1 CARTON | 05/01/2024 | |
| **12** | | 100 in 1 BOTTLE; 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 | 08/19/2019 | |

## Labeler - Kenvue Brands LLC (118772437)

Revised: 2/2025 Kenvue Brands LLC