**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated**
**TOPCO ASSOCIATES LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Pain Relief 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 8 caplet 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.

**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)

**Inactive ingredients**

crosscarmellose sodium, lactose monohydrate, magnesium stearate, polethylene glycol, polyvinyl alcohol, povidone, purified water, sodium starch glycolate, starch corn, talc, titanium dioxide

**Questions?**

call **1-888-577-8033**

## PRINCIPAL DISPLAY PANEL - 200 Caplet Bottle Label

NDC 36800-150-20

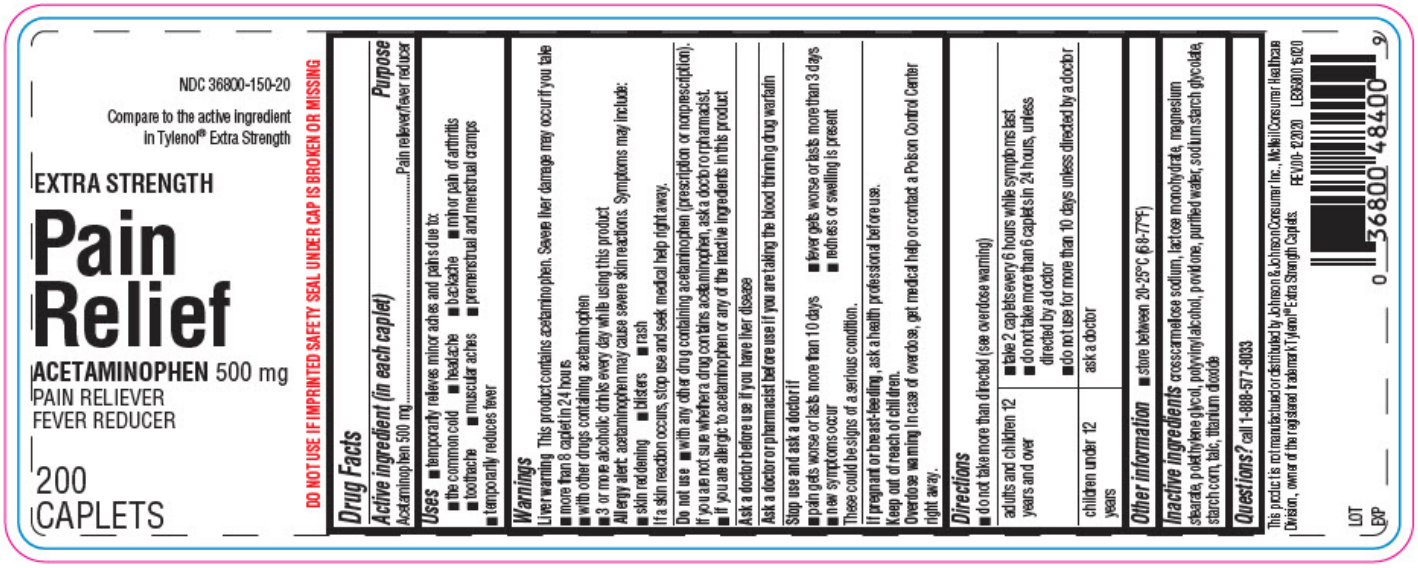
Compare to the active ingredient
in Tylenol® Extra Strength

EXTRA STRENGTH

Pain
Relief

ACETAMINOPHEN 500 mg
PAIN RELIEVER
FEVER REDUCER

200
CAPLETS




## PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet, coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:36800-961 |
| **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 |
|---|---|
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **Lactose Monohydrate** (UNII: EWQ57Q8I5X) | |
| **Magnesium Stearate** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **Talc** (UNII: 7SEV7J4R1U) | |
| **Titanium Dioxide** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | S150 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:36800-961-20 | 200 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part343 | 05/01/2021 | |

## Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 3/2021 TOPCO ASSOCIATES LLC