**ACETAMINOPHEN- acetaminophen tablet**
**Global Pharm Distribution 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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**Acetaminophen**

**DRUG FACTS:**

***Active ingredient (in each caplet)***

Acetaminophen 500 mg

**Purpose**

Pain reliever/fever reducer

**Inactive Ingredients:**

Corn Starch, Magnesium Stearate, Sodium Starch Glycolate, PVP.

**USES:**

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

**WARNINGS:**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take.

- more than 4000 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 a 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 - if you are not sure whether a drug contains acetaminophen - ask a doctor or pharmacist
- for more than 10 days for pains unless directed by a doctor

- for more than 3 days for fever unless directed by a doctor
- if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have:**
- liver disease.

**Ask a doctor 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
- ever gets worse or lasts more than 3 days
- 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. Quick medical attention is critical for adults as well as for children even if you do not noti ce any signs or symptoms.

**DIRECTIONS:**

do not take more than directed (see overdose warning).

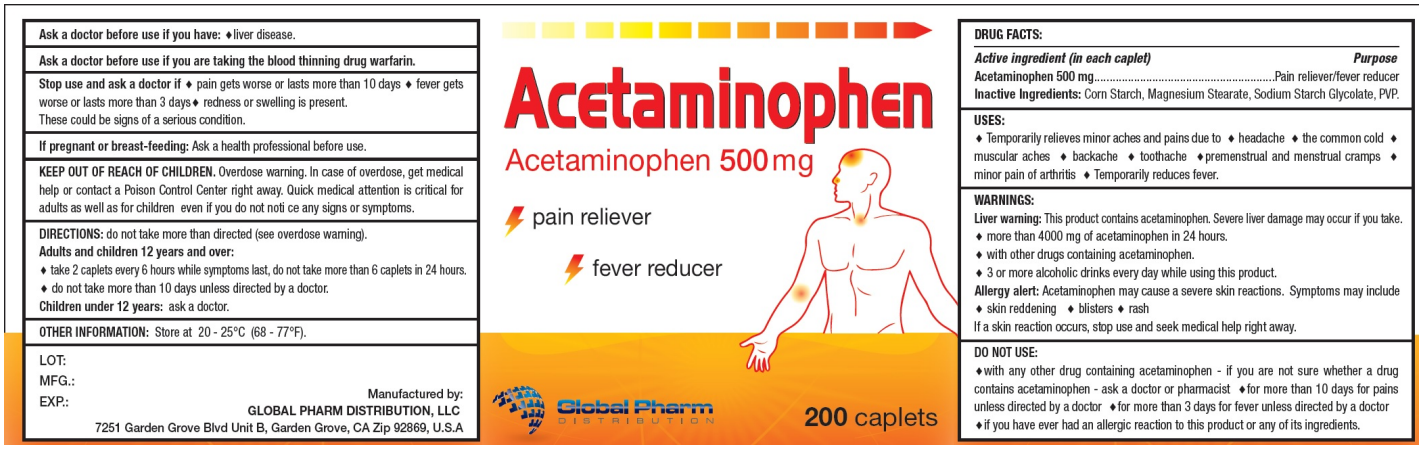
**Adults and children 12 years and over:**
- take 2 caplets every 6 hours while symptoms last, do not take more than 6 caplets in 24 hours.
- do not take more than 10 days unless directed by a doctor.

**Children under 12 years:** ask a doctor.

**OTHER INFORMATION:**

Store at 20 - 25°C (68 - 77°F).

**Package Labeling:**




## ACETAMINOPHEN

acetaminophen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69477-000 |
| **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** |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | OVAL | **Size** | 20mm |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:69477-000-01 | 200 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part343 | 11/01/2018 | |

**Labeler -** Global Pharm Distribution LLC (052115351)

Revised: 1/2020 Global Pharm Distribution LLC