**NON-ASPIRIN- acetaminophen tablet**
**ADVANCED FIRST AID, INC.**

*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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ACTIVE INGREDIENT IN EACH TABLET-

Acetaminophen 500 mg

pain reliever/fever reducer

Uses: temporarily relieves minor aches and pains associated with: • headaches • colds • toothache • minor arthritis pain • muscular aches • menstrual cramps • backache

Warnings:

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if: • you take more than 8 tablets in 24 hours • you take with other drugs containing acetaminophen (prescription or non-prescription) • you have 3 or more alcoholic drinks every day while using this product

Do not use: • with any other product containing acetaminophen • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor

When using this product do not exceed recommended dose.

Stop use and ask a doctor if: • symptoms do not improve • pain or fever persists or gets worse • new symptoms occur • redness or swelling is present

If pregnant or breast-feeding baby, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

Adults and children 12 years of age and older:  Take 2 tablets every 4 to 6 hours or as needed, do not exceed 8 tablets in 24 hours, or asdirected by a doctor.

Children under 12 years: Do not use this product: this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns.

Inactive Ingredients: corn starch, microcrystalline cellulose, povidone, sodium starch glycolate, and stearic acid


# NON-ASPIRIN

acetaminophen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67060-210 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 500 |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND | **Size** | 12mm |
| **Flavor** | | **Imprint Code** | FR1 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67060-210-68 | 100 in 1 CARTON | 04/10/2015 | |
| **1** | | 2 in 1 PACKET; Type 0: Not a Combination Product | | |
| **2** | NDC:67060-210-67 | 250 in 1 CARTON | 04/10/2015 | |
| **2** | | 2 in 1 PACKET; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part343 | 04/10/2015 | |

## Labeler - ADVANCED FIRST AID, INC. (114477180)

## Registrant - ADVANCED FIRST AID, INC. (114477180)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| ULTRA SEAL CORPORATION | | 085752004 | pack(67060-210) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| ULTRA TAB LABORATORIES, INC. | | 151051757 | manufacture(67060-210) |

Revised: 4/2015 ADVANCED FIRST AID, INC.