**FAMILY WELLNESS ACETAMINOPHEN- acetaminophen tablet, film coated**
**Family Dollar Services 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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**Family Dollar Services, Inc. Acetaminophen Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 500 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- 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 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 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 at 20-25°C (68-77°F)

**Inactive ingredients**

croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, mica-based pearlescent pigment, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid

**Questions or comments?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT OF TYLENOL® EXTRA STRENGTH RAPID RELEASE GELS

EXTRA STRENGTH

Acetaminophen

100% SATISFACTION GUARANTEED OR YOUR MONEY BACK

Pain Reliever/Fever Reducer

For Adults

Rapid Release

100 CAPLETS – 500 mg EACH

ACTUAL SIZE

OTC network


# FAMILY WELLNESS ACETAMINOPHEN

acetaminophen tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:55319-407 |
| **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) | |
| **CROSPOVIDONE (15 MPA.S AT 5%)** (UNII: 68401960MK) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | RED | **Score** | no score |
| **Shape** | OVAL | **Size** | 18mm |
| **Flavor** | | **Imprint Code** | 3S0 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:55319-407-71 | 1 in 1 CARTON | 06/22/2020 | |
| **1** | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:55319-407-78 | 1 in 1 CARTON | 06/18/2020 | |
| **2** | | 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 not final | part343 | 06/18/2020 | |

## Labeler - Family Dollar Services Inc (024472631)

Revised: 6/2020 Family Dollar Services Inc