**PAIN RELIEF REGULAR STRENGTH- acetaminophen tablet**
**Chain Drug Marketing Association**

*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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**Quality Choice Pain Relief Regular Strength Tablets - 2014-1027**

***Drug Facts***

**Active ingredient (in each tablet)**

Acetaminophen 325 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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**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 the user is allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if the user has** liver disease.

**Ask a doctor or pharmacist before use if the user is** taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 tablets every 4 to 6 hours while symptoms last<br>■ do not take more than 10 tablets in 24 hours<br>■ do not use for more than 10 days unless directed by a doctor |
| children 6-11 years | ■ take 1 tablet every 4 to 6 hours while symptoms last<br>■ do not take more than 5 tablets in 24 hours<br>■ do not use for more than 5 days unless directed by a doctor |
| children under 6 years | ■ ask a doctor |

**Other information**

- store between 20-25°C (68-77°F)
- retain carton for complete product information

**Inactive ingredients**

povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**PRINCIPAL DISPLAY PANEL**

NDC 63868-082-10

QUALITY CHOICE

†Compare to the Active Ingredient in TYLENOL® Regular Strength Tablets

Regular Strength

Pain Relief

Pain Reliever / Fever Reducer

Acetaminophen, 325 mg

100 Tablets – 325 mg each


# PAIN RELIEF REGULAR STRENGTH

acetaminophen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63868-082 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |

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

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | M2A3;57344 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:63868-082-10 | 1 in 1 CARTON | 06/13/2014 | |
| **1** | | 100 in 1 BOTTLE, PLASTIC; 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 | 06/13/2014 | |

**Labeler -** Chain Drug Marketing Association (011920774)

Revised: 12/2018 Chain Drug Marketing Association