

PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated
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.

Quality Choice Pain Relief Extra Strength Cool Taste Caplets - 2014-1027

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. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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

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 (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 | <ul style="list-style-type: none"> ▪ take 2 caplets every 6 hours while symptoms last ▪ swallow whole – do not crush, chew, or dissolve ▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor ▪ do not use for more than 10 days unless directed by a doctor |
| children under 12 years | <ul style="list-style-type: none"> ▪ ask a doctor |

Other information

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

Inactive ingredients

acesulfame potassium, flavor, hypromellose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-503-50

QUALITY CHOICE

†Compare to **TYLENOL®** Extra Strength Cool Caplets active ingredient

Extra Strength

Pain Relief Cool Taste Caplets

SEE NEW WARNINGS & DIRECTIONS

Pain Reliever / Fever Reducer

Acetaminophen

Instant Cooling Sensation

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-503 |
| 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 |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | MINT | Imprint Code | AAA;1098 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63868-503-50 | 1 in 1 CARTON | 03/15/2007 | |
| 1 | | 50 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 | 03/15/2007 | |

Labeler - Chain Drug Marketing Association (011920774)