

ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, coated
FSA Store Inc.

1004-CRM-2023-0111

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. 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 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▪ 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

hypromellose, mineral oil, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

caring mill™

NDC 81522-104-04

†Compare to the active ingredient in Tylenol® Extra Strength Caplets

Extra Strength

Acetaminophen

500 mg

Pain Reliever/Fever Reducer

For Adults

100 CAPLETS - 500 MG EACH

Actual Size



ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81522-104 |
| 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 |
|-----------------|----------|
|-----------------|----------|

| | |
|---|--|
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| 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 | | Imprint Code | M2A4;57344 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81522-104-04 | 1 in 1 CARTON | 01/11/2023 | |
| 1 | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:81522-104-06 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/03/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013 | 01/11/2023 | |

Labeler - FSA Store Inc. (049283340)

Revised: 10/2024

FSA Store Inc.