

EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet
SPIRIT PHARMACEUTICALS LLC

EXTRA STRENGTH 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:
- 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 | ask a doctor |

Other information

- **each caplet contains:** magnesium 0.43 mg
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or inner Safety Seal is broken or missing**

Inactive ingredients

Hypermellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-333-9792

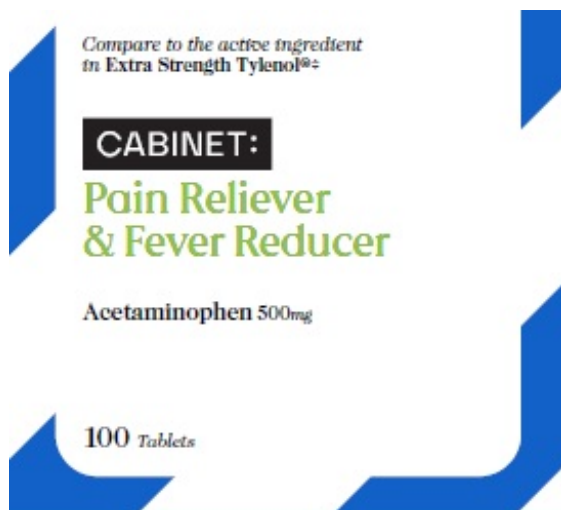
PRINCIPAL DISPLAY PANEL

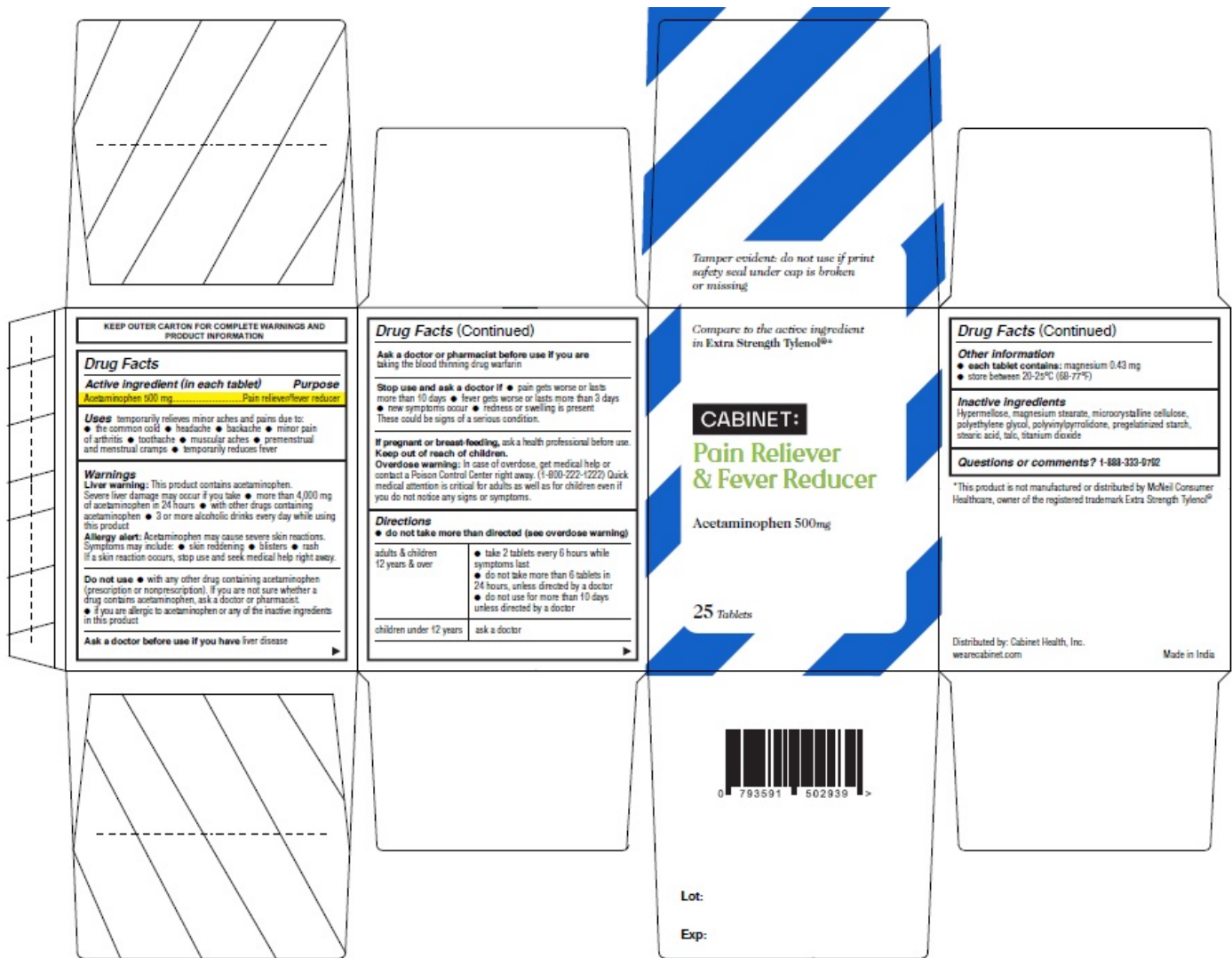
Compare TO THE ACTIVE INGREDIENT IN
EXTRA STRENGTH TYLENOL® CAPLETS†
EXTRA STRENGTH

Acetaminophen

Acetaminophen 500 mg
Pain Reliever/ Fever reducer

25 CAPLET/ 100 CAPLET





EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68210-4097 |
| 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 |
|---|----------|
| HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2) | |
| MAGNESIUM STEARATE (UNII: 70097M6130) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |

| | |
|---|--|
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 18mm |
| Flavor | | Imprint Code | S500 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68210-4097-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 07/02/2020 | |
| 2 | NDC:68210-4097-2 | 1 in 1 PACKAGE | 07/02/2020 | |
| 2 | | 25 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 Drug | M013 | 07/02/2020 | |

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC