

8 HOUR PAIN RELIEF- acetaminophen tablet, extended release
STRATEGIC SOURCING SERVICES LLC

1201A-FST-2023-0609

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - backache
 - minor pain of arthritis
 - toothache
 - premenstrual and menstrual cramps
 - headache
 - the common cold
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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 8 hours with water▪ swallow whole; do not crush, chew, split 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">▪ do not use |

Other information

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

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose,

polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

Call 833-358-6431 Monday to Friday 9 am to 7 pm EST

PRINCIPAL DISPLAY PANEL

NDC 70677-1123-1

COMPARE TO TYLENOL® 8HR ACTIVE INGREDIENT

Foster & Thrive™

8 Hour Pain Relief

Acetaminophen

Extended-Release Tablets, 650 mg

PAIN RELIEVER/FEVER REDUCER

For up to 8 Hour Relief of Minor Muscle Aches and Pain

ACTUAL SIZE

100 CAPLETS** - 650 MG EACH

**CAPSULE-SHAPED BI-LAYER TABLETS



8 HOUR PAIN RELIEF

acetaminophen tablet, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70677-1123

Route of Administration

ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5) | |
| HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|----------|---------|--------------|----------|
| Color | white | Score | no score |
| Shape | CAPSULE | Size | 19mm |
| Flavor | | Imprint Code | G650 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70677-1123-1 | 1 in 1 CARTON | 06/09/2023 | |
| 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA211544 | 06/09/2023 | |

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)