

**PAIN RELIEVER- acetaminophen tablet, extended release**  
**STRATEGIC SOURCING SERVICES LLC**

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**1201A-SMK-2022-0923**

***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"><li>▪ take 2 caplets every 8 hours with water</li><li>▪ swallow whole; do not crush, chew, split or dissolve</li><li>▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li><li>▪ do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>▪ do not use</li></ul>

### **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?**

833-358-6431 Monday to Friday 9:00am to 7:00pm EST

### **PRINCIPAL DISPLAY PANEL**

sunmark®

COMPARE TO TYLENOL® 8HR ACTIVE INGREDIENT†

NDC 70677-0168-1

8 hour

pain reliever

Acetaminophen Extended-Release Tablets, 650 mg

Pain Reliever / Fever Reducer

- For up to 8 Hours Relief of Minor Muscle Aches and Pain

100 CAPLETS\*\* - 650 MG EACH

\*\* Capsule-Shaped Bi-Layer Tablets

ACTUAL SIZE



## PAIN RELIEVER

acetaminophen tablet, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0168
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:70677-0168-1	1 in 1 CARTON	09/23/2022	11/30/2025
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	09/23/2022	11/30/2025

**Labeler** - STRATEGIC SOURCING SERVICES LLC (116956644)