

**ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, film coated**  
**NCS HealthCare of KY, LLC dba Vanguard Labs**

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**Acetaminophen Caplets 500mg 8409 Time-Cap**

**DRUG FACTS**

***Active ingredient (in each caplet)***

Acetaminophen 500 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - 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 using and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or last 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 (1-800-222-1222) right away. 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**

- 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**

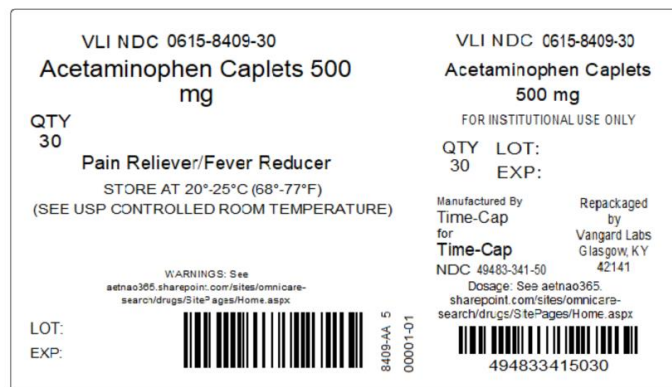
ask a doctor

***Other information***

- SODIUM FREE
- store between 20-25°C (68-77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

\*may contain this ingredient

### PRINCIPAL DISPLAY PANEL - UNIT DOSE



## ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-8409(NDC:49483-341)
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)	

POVIDONE (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL ((caplet))	Size	17mm	
Flavor		Imprint Code	TCL341	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8409-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/05/2021	
2	NDC:0615-8409-30	6 in 1 BOX, UNIT-DOSE	10/06/2021	
2		5 in 1 BLISTER PACK; 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	07/18/2011	

**Labeler -** NCS HealthCare of KY, LLC dba Vanguard Labs (050052943)

## Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vanguard Labs		050052943	repack(0615-8409)

Revised: 11/2023

NCS HealthCare of KY, LLC dba Vanguard Labs