

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

Acetaminophen Caplets 8409

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

Inactive ingredients hypromellose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, titanium dioxide
 *may contain this ingredient

Questions or comments? Call 1-877-290-4008

Manufactured by:
Time-Cap Labs, Inc
7 Michael Avenue
Farmingdale, NY 11735
341R 0922

PRINCIPAL DISPLAY PANEL - BINGO CARD



VU NDC 0615-8409-39
Acetaminophen Caplets 500 mg
 LOT 8409-
 EXP
 8409-AA-39 v00
 QTY
 30

Mfg By Time-Cap
 (NDC 49483-341-50)
 PKG BY VANGARD
 GLASGOW, KY 42141

See Warnings on Reverse
 Pain Reliever/Fever Reducer
 TAMPER EVIDENT

(Time-Cap NDC 49483-341-50)
Acetaminophen Caplets 500 mg

Received: _____

24	16	8
31	23	15
30	22	14
29	21	13
28	20	12
27	19	11
26	18	10
25	17	9
Start Date	Start Time	

See Bottle Label for Drug Facts and full labeling information.

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- 3 or more alcoholic drinks every day while using this product.

See Bottle Label for additional warning information.

Store between 20°-25°C (68°-77°F) excursions permitted between 15°-30°C (59°-86°F).

FOR INSTITUTIONAL USE ONLY

<p>Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Caplet 500 mg LOT 8409- 4948334150</p>	<p>Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Caplet 500 mg LOT 8409- 4948334150</p>	<p>Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Caplet 500 mg LOT 8409- 4948334150</p>	<p>8409-AA-B-v02 Vanguard Labs Glasgow, KY 42141 LOT 8409- 4948334150</p>
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16	8	30	23
29	22	28	21
27	20	26	19
25	18	25	18

 **Omnicare** 24 17 9 1
 The overall configuration of this package is a trademark of Omnicare, Inc.

PRINCIPAL DISPLAY PANEL - UNIT DOSE

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 Caplet 500 mg
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8409-AA-UD1-V01

VG NDC 0615-8409-30 Acetaminophen Caplets 500 mg Pain Reliever/Fever Reducer QTY 30 See Bottle Label for Drug Facts and full labeling information. Store between 20°-25°C (68°-77°F) excursions permitted between 15°-30°C (59°-86°F). 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. See Bottle Label for additional warning information. LOT:  8409AA 7 00001 01 EXP:	VG NDC 0615-8409-30 Acetaminophen Caplets 500 mg Pain Reliever/Fever Reducer FOR INSTITUTIONAL USE ONLY QTY 30 LOT: EXP: Manufactured By Time-Cap or Time-Cap NDC 49483-341-50 Repackaged by Vanguard Labs Glasgow, KY 42141  494833415030
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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	04/30/2026
2	NDC:0615-8409-30	6 in 1 BOX, UNIT-DOSE	10/06/2021	03/31/2026
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0615-8409-05	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/25/2024	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/18/2011	04/30/2026

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: 8/2024

NCS HealthCare of KY, LLC dba Vanguard Labs