

ACETAMINOPHEN- acetaminophen tablet
NCS HealthCare of KY, LLC dba Vanguard Labs

340R-TCL 49483-340 APAP 325 MG

DRUG FACTS

Active ingredient (in each tablet)

Acetaminophen 325 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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if:

- adult takes more than 4,000 mg of acetaminophen in 24 hours.
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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

- take 2 tablets every 4 to 6 hours while symptoms last
- do not take more than 10 tablets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

children 6 years to under 12 years

- take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by a doctor

children under 6 years

ask a doctor

OTHER INFORMATION

Other information

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

Inactive ingredients

povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

*may contain this ingredient

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

Manufactured by: Time-Cap Labs, Inc.,

7 Michael Avenue, Farmingdale, NY 11735

340R 1022

PRINCIPAL DISPLAY PANEL



(Time-Cap NDC 49483-340-10)

Acetaminophen Tablets (Two 325 mg Tablets)

See Warning on Reverse Pain Reliever/Fever Reducer

Mfg By Time-Cap (NDC 49483-340-10) PKG BY VANGUARD GLASGOW, KY 42141

TAMPER EVIDENT 8398-AA-67 v01

30	23	15	8
29	22	14	7
28	21	13	6
27	20	12	5
26	19	11	4
25	18	10	3
24	17	9	2
17	9	1	1

The overall configuration of this package is a trademark of Omnicare, Inc.

Received:

31	24	16	8
30	23	15	7
29	22	14	6
28	21	13	5
27	20	12	4
26	19	11	3
25	18	10	2
24	17	9	1

Start Date _____ Start Time _____

See Bottle Label for Drug Facts and full labeling information.

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.

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

FOR INSTITUTIONAL USE ONLY

Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Tablets (Two 325 mg Tablets) LOT 8398	Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Tablets (Two 325 mg Tablets) LOT 8398	Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Tablets (Two 325 mg Tablets) LOT 8398	Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Tablets (Two 325 mg Tablets) LOT 8398
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ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-8398(NDC:49483-340)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL340
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8398-67	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/22/2021	09/30/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/15/2011	09/30/2026

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(0615-8398)

Revised: 6/2024

NCS HealthCare of KY, LLC dba Vanguard Labs