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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

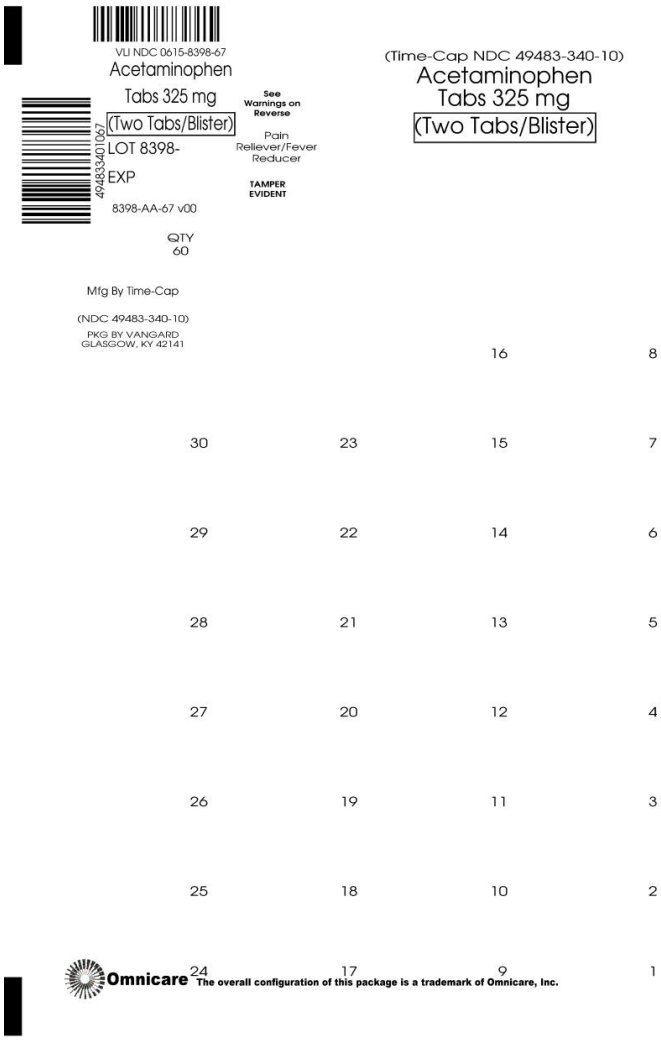
Questions or comments? **call 1-877-290-4008**

Manufactured by: Time-Cap Labs, Inc.,

7 Michael Avenue, Farmingdale, NY 11735

340R 1022

PRINCIPAL DISPLAY PANEL



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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/15/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vangard Labs		050052943	repack(0615-8398)

Revised: 12/2022 NCS HealthCare of KY, LLC dba Vangard Labs