

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

Timely 699R Arthritis Pain Relief- Acetaminophen Extended-Release Tablets
USP, 650 mg

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - premenstrual and menstrual cramps
 - the common cold
 - headache
 - toothache
- 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

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

under 18 years of age

- ask a doctor

Other information

- store between 20-25°C (68-77°F)
- The FDA approved Dissolution methods differ from USP

Inactive ingredients

carnauba wax, hydroxyethylcellulose, hypromellose, povidone, pregelatinized starch, sodium starch glycolate, magnesium stearate, microcrystalline cellulose, triacetin, titanium dioxide

Questions or comments?

Call 1-877-290-4008

Contains No Aspirin

Principal Display Panel

VG NDC 0615-8425-39
Acetaminophen
Extended-Release
Tablets USP, 650 mg
LOT 8425-
EXP
QTY 30

See
Warning on
Reverse

Pain Reliever/
Fever Reducer

(Time-Cap NDC 49483-699-01)

Acetaminophen
Extended-Release
Tablets USP, 650 mg

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:

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- with other drugs containing acetaminophen
- 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)

FOR INSTITUTIONAL USE ONLY

<p>Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Extended-Release Tablet USP, 650 mg</p> <p>LOT 8425- 4948369901</p>	<p>Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Extended-Release Tablet USP, 650 mg</p> <p>LOT 8425- 4948369901</p>	<p>Pkg by Vanguard, Glasgow, KY 42141 Acetaminophen Extended-Release Tablet USP, 650 mg</p> <p>LOT 8425- 4948369901</p>	<p>8425-AA-B v03 Vanguard Labs Glasgow, KY 42141</p> <p>LOT 8425- 4948369901</p>
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Mfg By Markans for Time-Cap (NDC 49483-699-01) PKG BY VANGARD GLASSGOW, KY 42141

TAMPER EVIDENT 8425-AA-39 v01

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

24 17 9 1

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

ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-8425(NDC:49483-699)
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	

Product Characteristics

Color	white (White to off white)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8425-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	10/04/2021	

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

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(0615-8425)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vanguard Labs		050052943	repack(0615-8425)

Revised: 6/2024

NCS HealthCare of KY, LLC dba Vanguard Labs