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

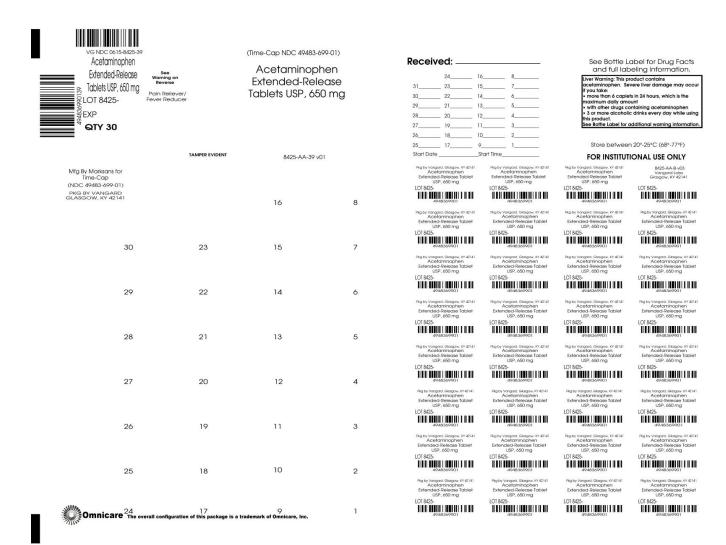
carnauba wax, hydroxyethylcellulose, hypromellose, povidone, pregelatinized starch, sodium starch glycolate, magnesium stearate, microcrystalline cellulose, triacetin, titanium dioxide

Questions or comments?

Call 1-877-290-4008

Contains No Aspirin

Principal Display Panel



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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 650 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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)	

Product Characteristics

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

Packaging

ı	i dekuging			
	# 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

. Id. Nothing Intermediate			
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 Vangard Labs (050052943)

HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)

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 Vangard Labs		050052943	repack(0615-8425)	

Revised: 6/2024 NCS HealthCare of KY, LLC dba Vangard Labs