

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

Acetaminophen Extended Release Tablets 650 mg

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 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 everyday 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 drugs 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 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• ask a doctor

OTHER INFORMATION

- store between 20-25°C (68-77°F)

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-8624(NDC:70010-160)
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
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8624-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/10/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	02/15/2022	

Labeler - NCS HealthCare of KY, LLC dba Vanguard Labs (050052943)**Registrant** - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vanguard Labs		050052943	repack(0615-8624)

Revised: 2/2026

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