ACETAMINOPHEN - acetaminophen tablet, extended release
CVS Pharmacy, Inc.

Drug Facts

Active ingredient (in each extended-release tablet)

Acetaminophen USP 650 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 tablets 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 and children 12 years and over	• take 2 tablets every 8 hours with water • swallow whole; do not crush, chew, split or dissolve • do not take more than 6 tablets in 24 hours • do not use for more than 10 days unless directed by a doctor.
children under 12 years	• do not use

Other information

- store at 20º to 25ºC (68º to 77ºF). Avoid excessive heat 40ºC (104ºF).
- **do not use if carton is opened or foil inner seal is broken**
- Meets USP dissolution test 3

Inactive ingredients

colloidal silicon dioxide, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maize), sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?
call **1-855-274-4122**

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895

CVS.com®
1-800-SHOP CVS

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (24 Tablets Bottle)

CVSHealth® **Tablets**
NDC 69842-635-07

8HR Muscle
Aches & Pain
ACETAMINOPHEN
EXTENDED-RELEASE
TABLETS USP, 650 mg
Pain Reliever/Fever Reducer

DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN

24 EXTENDED-RELEASE
TABLETS 650 mg EACH

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (24 Tablets Container Carton)

CVS Health®

Compare to the active ingredient in
Tylenol® 8HR Muscle Aches & Pain*

Tablets

NDC 69842-635-07

8HR Muscle Aches & Pain
ACETAMINOPHEN

EXTENDED-RELEASE TABLETS USP, 650 mg
Pain Reliever/Fever Reducer

For up to 8 hours of relief of minor muscle aches & pain

Contains No Aspirin

24 EXTENDED-RELEASE TABLETS 650 mg EACH

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-635
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE (White to Off-White)	**Score**	no score
Shape	CAPSULE (Caplet)	**Size**	19mm
Flavor		**Imprint Code**	I;06
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-635-07	1 in 1 CARTON	10/13/2022	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207229	10/13/2022	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(69842-635) , MANUFACTURE(69842-635)