

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• do not use

Other information

- store at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F).
- **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

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**

	Tablets NDC 69842-635-07	Purpose Pain reliever/fever reducer	<p>8HR Muscle Aches & Pain ACETAMINOPHEN</p> <p>EXTENDED-RELEASE TABLETS USP, 650 mg</p> <p>Pain reliever/Fever reducer</p> <p>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</p> <p>24 EXTENDED-RELEASE TABLETS 650 mg EACH</p> <p>Do not use if foil inner seal is broken. Contains No Aspirin.</p> <p>Active ingredient (in each extended-release tablet): Acetaminophen USP (650 mg)</p> <p>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</p> <p>Warnings: Liver warning: This product contains acetaminophen. Severe liver damage occurs if you take too much acetaminophen. Do not drink alcohol while taking this product. Do not take more than the maximum daily amount. Do not take 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 redness ■ hives ■ rashes ■ itchy skin ■ a skin reaction occurs. Stop use and seek medical help right away. Do not use ■ with any other drug containing acetaminophen. ■ with other acetaminophen products. ■ If you are not sure whether a condition is 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 ■ you get waves of dizziness ■ you feel lightheaded ■ you have trouble breathing ■ you have a severe skin reaction. ■ if you are pregnant, 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). Black medical warning: Do not use if you have any of the following conditions: ■ you are taking or have taken the anti-folate medicine methotrexate, ■ you are taking or have taken the anti-cancer drug capecitabine, ■ you are taking or have taken the anti-cancer drug irinotecan, ■ you are taking or have taken the anti-cancer drug vinorelbine, ■ you are taking or have taken the anti-cancer drug docetaxel, ■ you are taking or have taken the anti-cancer drug paclitaxel, ■ you are taking or have taken the anti-cancer drug carboplatin, ■ you are taking or have taken the anti-cancer drug cisplatin, ■ you are taking or have taken the anti-cancer drug etoposide, ■ you are taking or have taken the anti-cancer drug ifosfamide, ■ you are taking or have taken the anti-cancer drug mitomycin, ■ you are taking or have taken the anti-cancer drug topotecan, ■ you are taking or have taken the anti-cancer drug paclitaxel, ■ you are taking or have taken the anti-cancer drug docetaxel, ■ you are taking or have taken the anti-cancer drug irinotecan, ■ you are taking or have taken the anti-cancer drug vinorelbine, ■ you are taking or have taken the anti-cancer drug carboplatin, ■ you are taking or have taken the anti-cancer drug cisplatin, ■ you are taking or have taken the anti-cancer drug etoposide, ■ you are taking or have taken the anti-cancer drug ifosfamide, ■ you are taking or have taken the anti-cancer drug mitomycin, ■ you are taking or have taken the anti-cancer drug topotecan.</p> <p>Other information: ■ Store at 20° to 25° (68° to 77°F). Avoid excessive heat (0° to 15°). ■ Invert USP Assay/Control test. Inactive ingredients: Colloidal silicon dioxide, hydroxyethyl cellulose, polyethylene glycol, croscarmellose sodium, croscarmellose sodium cross-linked polyacrylate, croscarmellose sodium (aqueous), croscarmellose sodium cross-linked polyacrylate, croscarmellose sodium (aqueous), croscarmellose sodium cross-linked polyacrylate, croscarmellose sodium (aqueous), croscarmellose sodium cross-linked polyacrylate, croscarmellose sodium (aqueous).</p> <p>Questions or comments? call 1-855-214-112</p> <p>Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2023 CVS/pharmacy Code: TS/DRUGS/22/2009 Made in India V-31869</p> <p style="text-align: right;">* P 14-32-669 LM-5159 NVZ</p>
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* 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 MPAS AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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	l;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)

