

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release
CVS PHARMACY INC**

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

For upto 8 hour relief of minor muscle aches & pain

Contains no aspirin

Active ingredient

(in each caplet)
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

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

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 of age and over

■ 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

children under 12 years

■ do not use

Other information

■ store between 20-25°C (68-77°F)

■ **do not use if foil inner seal is broken or missing**

Inactive ingredients

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Principle Display Pannel



NDC 69843-257-00



actual size

8 HR MUSCLE ACHES & PAIN

Acetaminophen Extended-Release Tablets USP, 650 mg Pain Reliever / Fever Reducer

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

200 CAPLETS† 650 mg EACH

†Capsule-Shaped Bi-Layer Tablets

For up to 8 Hours Relief of
Minor Muscle Aches & Pain
Contains No Aspirin

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

IMPORTANT: READ THE DIRECTIONS AND WARNINGS BEFORE USE

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)

Acetaminophen USP 650 mg. 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 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:

- redness
- itching
- blistering
- swelling
- hives
- skin peeling

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

- your 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

Distributed by: CVS Pharmacy, Inc.
© 2023 CVS Pharmacy. All rights reserved.
CVS.com



LOT

EXP

(CONTINUED ON BACK OF LABEL)

To simulate a printed label, fold along dotted line.

Inside (adhesive side)

Drug Facts (continued)

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:
 - 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

children under 12 years

- do not use

Other information

- store between 20°-25°C (68°-77°F)
- do not use if foil inner seal is broken or missing

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

*This product is not manufactured or distributed by Kenace Brands LLC, owner of the registered trademark, "Tylenol" 8 HR Muscle Aches & Pain.



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-297
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
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	white (White to off white colored)	Score	no score
Shape	OVAL (Capsule shaped, biconvex intact film coated tablets)	Size	19mm
Flavor		Imprint Code	G;650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-297-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2020	
2	NDC:69842-297-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	01/30/2020	

Labeler - CVS PHARMACY INC (062312574)

Revised: 12/2025

CVS PHARMACY INC