

8HR ARTHRITIS PAIN RELIEF- acetaminophen 650mg tablet, extended release
CVS Pharmacy

CVS Acetaminophen Extended Release Tablets USP 650 mg

Drug Facts

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	<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)
- The FDA approved dissolution methods differ from USP

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

Questions or comments? Call **1-877-290-4008**

Adhesive Area

Contains No Aspirin

Questions or comments? Call 1-877-290-4008

Inactive ingredients

camellia wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Other information

■ store between 20-25°C (68-77°F)

■ The FDA approved dissolution methods differ from USP

under 18 years of age

■ ask a doctor

■ 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

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Directions Do not take more than directed.

See overdose warning

Stop use and ask a doctor if

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■ fever gets worse or lasts more than 3 days

■ new symptoms occur ■ redness or swelling is present

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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.

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

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

Drug Facts (continued)

Allergy alert: acetaminophen may cause severe skin reactions.

Symptoms may include: ■ skin reddening ■ blisters ■ rash



8 HR ARTHRITIS PAIN RELIEF

Acetaminophen

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

Compare to Tylenol® 8 HR
Arthritis Pain active ingredient*

THIS PACKAGE FOR HOUSEHOLDS
WITHOUT YOUNG CHILDREN

For Temporary Relief of
Minor Arthritis Pain
Lasts up to 8 Hours

100 CAPLETS,[†]
650 mg EACH
[†]Capsule-Shaped
Bi-Layer Tablets



actual
size

NDC 51316-969-01

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOR
SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 650 mg.....Pain reliever/fever reducer

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Drug Facts (continued under label)

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Tylenol® 8 HR Arthritis Pain.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com® 1-800-540-CVS

Made in India

B99R 0525

FPO 80%
UPC# 050428004531

1935588

#

X XXXXXX XXXXXX X

Varnish Omit Area

LOT:

EXP:



1/16"
Margin

Inside

Outside

8HR ARTHRITIS PAIN RELIEF

acetaminophen 650mg tablet, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51316-969

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	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
TRIACETIN (UNII: XHX3C3X673)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
Product Characteristics				
Color	white (White to Off-White)		Score	no score
Shape	OVAL		Size	19mm
Flavor			Imprint Code	71
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-969-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA215486	07/01/2025	

Labeler - CVS Pharmacy (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(51316-969)