

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

**Arthritis
Pain Reliever**

ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg

PAIN RELIEVER / FEVER REDUCER

ARTHRITIS 8 HOURCAPLETS

- **For the temporary relief of minor arthritis pain**
- **Lasts up to 8 hours**

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

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

■ 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

■ ask a doctor

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.

PDP



Compare to the active ingredient in Tylenol® 8HR Arthritis Pain*

Caplets[†]

8HR Arthritis Pain Relief

ACETAMINOPHEN

EXTENDED-RELEASE TABLETS USP, 650 mg

**Pain Reliever/
Fever Reducer**

For the temporary relief of minor arthritis pain

100 CAPLETS[†], 650 mg EACH
CAPSULES WITH 3-LAYER TABLETS



Actual Size

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Important: Read all product information before using.

Drug Facts

Active ingredient (in each caplet) Pain relief time: faster
Acetaminophen USP 650 mg

Uses

- Temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual and menstrual cramps
 - the common cold
 - teething
- 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
- 5 or more alcoholic drinks every day while using this product

Other risks: Acetaminophen may cause severe skin reactions. Symptoms may include: skin rash, skin peeling, blisters, hives, and

If a skin reaction occurs, stop use and seek medical help right away.

#193588 (CONTINUED ON BACK OF LABEL)

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One CVS Drive
Woonsocket, RI 02896
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PEEL HERE

Inside (adhesive side)

Drug Facts (continued)

Do not use

- with any other drug containing acetaminophen (paracetamol or parasetamol).
- 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
- there 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. (1-800-525-0223) Usual 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

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or crush
- 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

- ask a doctor

Other information

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

Inactive ingredients

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

Questions or comments?

contact 1-877-707-8282 Mon-Fri 8:00 AM EST to 8:00 PM PST
† This product is not manufactured or distributed by McKel-Corcoran, Inc. Highfructose dextrose or Tylenol® 8HR Arthritis Pain.



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-322
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: O8232NY3S)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
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:69842-322-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	
2	NDC:69842-322-10	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	02/01/2021	

Labeler - CVS PHARMACY INC (062312574)

Revised: 12/2023

CVS PHARMACY INC