

**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

| | |
|---|--|
| 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

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|-----------------|--|---------------------|----------|
| 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: 12/2023

CVS PHARMACY INC