

ACETAMINOPHEN- acetaminophen tablet
MAJOR PHARMACEUTICALS

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

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 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

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

MAJOR NDC 0904-7314-27
Compare to the active ingredient
in Tylenol® 8 HR Arthritis Pain†

8 HR Arthritis Pain Relief
Acetaminophen
Extended-Release
Tablets USP, 650 mg
Pain Reliever/Fever Reducer

8 Hour
For the Temporary Relief
of Minor Arthritis Pain
Contains No Aspirin

**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**

400 Caplets™ 650 mg each
(**Capsule-Shaped Bi-Layer Tablets)

Actual Size

Important: Read all product information before using.
Do not use if foil inner seal is broken or missing.

**TO OPEN: PUSH AND
TURN CAP
READ THE LABEL**

MAJOR Pain reliever/fever reducer

Drug Facts

Active ingredient (in each caplet)
Acetaminophen USP 650 mg

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - minor pain of arthritis
 - backache
 - general aches and pains
 - premenstrual and menstrual cramps
 - headache
 - the common cold
 - toothache
- temporarily reduces fever

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than the recommended dose, which is the maximum daily amount.

Do not use if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Always alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- itching
- 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 if a drug contains acetaminophen, ask your 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:

- stomach pain or upset occurs
- stomach 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 breastfeeding, ask a health professional before use.

Keep out of reach of children.

For more information on this product, visit our website, get medical help or contact a Patient Control Center right away, 1-800-225-7222. Quick medical attention is critical for adults as well as for children when if you do not notice any signs or symptoms.

Directions

Do not take more than directed (see overdose warning).

- Take 2 caplets every 8 hours with water.
- Do not take more than 6 caplets in 24 hours.
- Do not take more than 10 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.

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Reg. 2122, M-622, Recalled No. 2013A

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Let Exp.

HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

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:0904-7314-27	400 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023	
2	NDC:0904-7314-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	03/03/2023	

Labeler - MAJOR PHARMACEUTICALS (191427277)

Revised: 12/2025

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