

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.

Purpose
Pain reliever/fever reducer

Drug Facts
Active ingredient (in each caplet)
Acetaminophen USP 650 mg.

Uses
Temporarily relieves minor aches and pains due to:
■ minor pain of arthritis
■ headache
■ the common cold
■ 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.
■ with other acetaminophen products every day while using this product.
■ Allergic alert: acetaminophen may cause severe skin reactions. Symptoms may include:
■ skin redness ■ hives ■ 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, 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:
■ you gain weight or lose 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.
Do not use if the seal is broken or missing, 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).
■ Take 2 caplets every 8 hours with water.
■ Do not take more than 6 caplets in 24 hours.
■ Do not use for more than 10 days unless directed by a doctor.
■ Ask a doctor.
under 18 years of age

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?
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Avenue, Philadelphia, PA 19104
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Lot Exp.



ACETAMINOPHEN acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7314
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

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: 12/2023

MAJOR PHARMACEUTICALS