

**ARTHRITIS PAIN- acetaminophen tablet, extended release
AMERIFOODS TRADING COMPANY**

1200A-FIR-2025-1120

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, unless directed by a doctor▪ 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)
- retain carton for complete product information and warnings

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose,

polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

NDC 61504-200-03

†COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® 8HR ARTHRITIS PAIN

FIRST STREET®

8 HOUR

Arthritis Pain

Acetaminophen

Extended-Release Tablets, 650 mg

Pain Reliever/Fever Reducer

For the temporary relief of minor arthritis pain

100 CAPLETS**

650 mg EACH

** Capsule-Shaped Bi-Layed Tablets

ACTUAL SIZE



ARTHRITIS PAIN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61504-200
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)

MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

POVIDONE K30 (UNII: U725QWY32X)

STARCH, CORN (UNII: 08232NY3SJ)

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61504-200-03	1 in 1 PACKAGE	11/20/2025	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	11/20/2025	

Labeler - AMERIFOODS TRADING COMPANY (626388680)

Revised: 11/2025

AMERIFOODS TRADING COMPANY