

ACETAMINOPHEN- acetaminophen tablet
American Health Packaging

Acetaminophen
Extended-Release
Tablets USP
Pain Reliever/Fever Reducer.
8492421/0825F

Drug Facts

Active Ingredient (in each extended release tablet)

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

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 tablets 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:

- take 2 tablets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 tablets 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 at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F)
- **do not use if carton is opened or foil inner seal is broken**
- USP Dissolution test is pending

Inactive ingredients

colloidal silicon dioxide, hydroxyethyl cellulose, hypromellose, magnesium stearate,

microcrystalline cellulose, povidone, pregelatinized starch (maize), sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?

- about the drug product, call Aurobindo Pharma USA at 1-855-274-4122
- about the packaging or labeling, call American Health Packaging at 1-800-707-4621

Contains No Aspirin

PACKAGING INFORMATION

American Health Packaging unit dose blisters contain drug product from BluePoint Laboratories as follows:

(650 mg / 30 UD) NDC 60687-924-21 packaged from NDC 68001-495

Distributed by:

American Health Packaging

Columbus, OH 43217

8492421/0825F

Principal Display Panel - Carton - 650 mg

NDC 60687-924-21

Acetaminophen

Extended-release Tablets USP
Pain Reliever/Fever Reducer

650 mg

30 Tablets (3 x 10)



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

NDC 60687-924-21

Acetaminophen

Extended-release Tablets USP
Pain Reliever/Fever Reducer

650 mg

30 Tablets (3 x 10)

<i>Drug Facts</i>	
Active ingredient (in each extended-release tablet)	Purpose
Acetaminophen USP 650 mg	Pain reliever/fever reducer
Uses See package insert for complete Drug Facts information.	
Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 tablets 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. See package insert for additional Drug Facts warnings.	
Directions ■ do not take more than directed, see package insert for overdose warning and complete Drug Facts information.	
Other Information ■ store at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F). ■ FOR YOUR PROTECTION: Do not use product if blister is torn or broken. ■ USP Dissolution test is pending	

Contains No Aspirin

The drug product contained in this package is from
NDC # 68001-495, BluePoint Laboratories.

Distributed by: American Health Packaging,
Columbus, Ohio 43217

792421
0492421/0825

NDC 60687- 924-21

Acetaminophen

Extended-release Tablets USP
Pain Reliever/Fever Reducer

650 mg

30 Tablets (3 x 10)

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

Drug Facts

Active Ingredient

Purpose

(in each caplet)

Acetaminophen USP, 650 mg.....Pain reliever/fever reducer

Uses

See package insert for complete Drug Facts information.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 6 tablets 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.

See package insert for additional Drug Facts warnings.

Directions

• do not take more than directed, see package insert for overdose warning and complete Drug Facts information.

Other Information • store at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F). • **FOR YOUR PROTECTION: Do not use product if blister is torn or broken.** • USP Dissolution test is pending

Contains No Aspirin

The drug product contained in this package is from
NDC # 68001-495, BluePoint Laboratories

Distributed by: American Health Packaging
Columbus, OH 43217

792421

0492421/0825

Principal Display Panel - Blister - 650 mg



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

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-924(NDC:68001-495)
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	
STARCH, CORN (UNII: O8232NY3SJ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIACETIN (UNII: XHX3C3X673)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
Product Characteristics				
Color	white ((White to Off-White))	Score	no score	
Shape	CAPSULE ((Caplet))	Size	19mm	
Flavor		Imprint Code	I;06	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-924-21	30 in 1 CARTON	02/01/2026	
1	NDC:60687-924-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA207229	02/01/2026		

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(60687-924)