

ACETAMINOPHEN- acetaminophen tablet, film coated, extended release
Amerisource Bergen

Acetaminophen

Drug Facts

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

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 and children 12 years and over	<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• do not use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none">• do not use

Other information

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

Inactive ingredients

crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions?

call **1-800-406-7984**

Distributed By:
AmerisourceBergen
1 West First Avenue
Conshohocken, PA 19428

PRINCIPAL DISPLAY PANEL - 50 Caplet Bottle Carton

GOOD
NEIGHBOR
PHARMACY®

Compare to Tylenol® 8 Hour
active ingredient†

NDC 46122-062-71

Use only as directed.

Last up to
8 Hour
acetaminophen extended-release tablets USP, 650 mg

Pain Reliever/Fever Reducer

- For up to 8 Hours Relief of Minor
Muscle Aches & Pain

DO NOT USE WITH
OTHER MEDICINES
CONTAINING
ACETAMINOPHEN

50 caplets*

(*capsule-shaped tablets)

Non Varnish Area

Batch No. Expiration Date



Drug Facts (continued)

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Inactive ingredients

croscollon, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions? call 1-800-406-7984

Contains No Aspirin

Keep the carton.
It contains important information.

[†]All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Tylenol® 8 Hour.

R0622

Distributed By:
AmersourceBogen
1 West First Avenue
Conshohocken, PA 19428
Questions or Concerns?
www.mgmp.com

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Drug Facts (continued)

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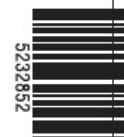
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ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-062
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, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPVIDONE (UNII: 2S7830E561)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL (Capsule Shaped)	Size	19mm
Flavor		Imprint Code	cor116
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-062-71	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
2	NDC:46122-062-78	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2002	

Labeler - Amerisource Bergen (007914906)

Registrant - Ohm Laboratories Inc. (051565745)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(46122-062)

Revised: 7/2022

Amerisource Bergen