

PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet
AmerisourceBergen (Good Neighbor Pharmacy) 46122

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks ever 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 a 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. 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
 - take 2 caplets every 6 hours while symptoms last
 - do not take more than 6 caplets in 24 hours
 - do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

corn starch, croscarmellose sodium*, hypromellose*, lactose monohydrate*, magnesium stearate*, maltodextrin*, medium-chain triglycerides*, mineral oil*, polydextrose*, polyethylene glycol*, polyvinyl alcohol*, povidone, purified water*, sodium starch glycolate, stearic acid*, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to **Tylenol® Extra Strength active ingredient†**

Extra Strength

Pain Reliever

Acetaminophen, 500 mg

Pain Reliever/Fever Reducer

Contains no aspirin

Caplets

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed By AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

Questions or Concerns?

Visit us at www.mygnp.com

Product Label

Lot / Exp.:
Product of:

PLD-C1080
FC000254



ABC#10164568



Distributed By AmeriSourceBergen
1300 Morris Drive, Chesterbrook, PA 19087
Visit us at www.mygrip.com

Drug Facts

Active ingredient
(in each caplet)

Acetaminophen 500 mg
Pain reliever/
fever reducer

Uses

- temporarily relieve minor pain such as:
- headache
- common cold
- backache
- minor pain of arthritis
- toothache
- muscular aches
- menstrual and menstrual cramps
- temporarily reduces fever

Warnings

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

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 - 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 redness
 - 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

Purpose

Pain reliever/
fever reducer

Drug Facts (continued)

- redness or swelling is present. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Compare to Tylenol® Extra Strength active ingredient†

NDC 46122-370-8

Extra Strength

Pain Reliever

acetaminophen 500 mg

Pain Reliever/Fever Reducer

Contains no aspirin
100 caplets

Good Neighbor Pharmacy Pain Reliever Caplets

PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46 122-370
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	TCL341;AV;0821;P500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-370-78	1 in 1 BOX	05/31/2016	12/31/2020
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
OTC MONOGRAPH NOT FINAL	part343	05/31/2016	12/31/2020

Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

