ACETAMINOPHEN REGULAR STRENGTH- acetaminophen tablet Amerisource Bergen

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.

Good Neighbor Pharmacy 44-678

Active ingredient (in each gelcap)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

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

- new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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
- adults and children 12 years and over
 - take 2 gelcaps every 4 to 6 hours while symptoms last
 - do not take more than 10 gelcaps in 24 hours, unless directed by a doctor
 - do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- avoid high humidity
- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn starch, croscarmellose sodium, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, propylene glycol, shellac glaze, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

Good Neighbor Pharmacy®

NDC 46122-430-78

Compare to Regular Strength Tylenol® active ingredient*

REGULAR STRENGTH

Acetaminophen

325 mg

Pain Reliever / Fever Reducer

100

Gelcaps 325 mg Each

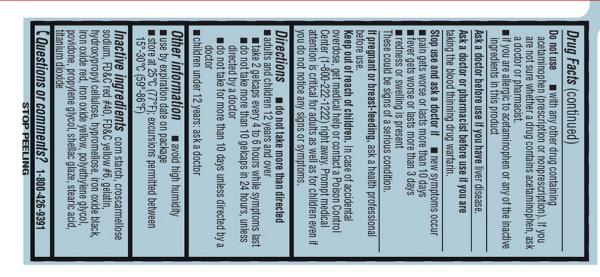
Actual Size

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

Distributed By AmerisourceBergan 1300 Morris Drive Chesterbrook, PA 19087 Questions or Concerns? www.mygnp.com

Good Neighbor Pharmacy Brand Products Satisfaction Guaranteed

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Regular Strength Tylenol®. 50844 REV0417A67812





Good Neighbor 44-678

ACETAMINOPHEN REGULAR STRENGTH

acetaminophen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-430	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
ı	ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	

CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDRO XYPRO PYL CELLULO SE, UNSPECIFIED (UNII: 9 XZ8 H6 N6 O H)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
SHELLAC (UNII: 46 N10 7B710)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	RED, WHITE	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	LB
Contains			

l	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:46122-430-78	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2015			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	07/24/2015		

Labeler - Amerisource Bergen (007914906)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		038154464	PACK(46122-430)	

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		868734088	PACK(46122-430)		

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	PACK(46122-430)	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(46122-430)

Revised: 9/2019 Amerisource Bergen