ACETAMINOPHEN- acetaminophen extra strength tablet
Akron Pharma Inc.

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.

Acetaminophen 500 mg
Extra Strength

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

To reduce fever and for the temporary relief of minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps.

Temporarily reduces fever.

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if
- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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 non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if the user has ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if the user has

- has liver disease
- is a child with pain of arthritis

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

Stop use and ask a doctor if:

- pain gets worse or lasts more than 10 days (for adults) or 5 days (for children)
- 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:

Taking more than the recommended dose (overdose) may cause liver damage. 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 & children 12 years and over	• take 2 tablets every 6 hours while symptoms last • do not take more than 6 tablets in 24 hours • do not use for more than 10 days unless directed by a doctor
child under 12 years	ask a doctor

Other information

- store at temperature 15° to 30°C (59° to 86°F)

Inactive Ingredients:

pregelatinized starch, microcrystalline cellulose, povidone (PVP K-30), colloidal silicon dioxide, croscarmellose sodium, stearic acid.

Questions or Comments?

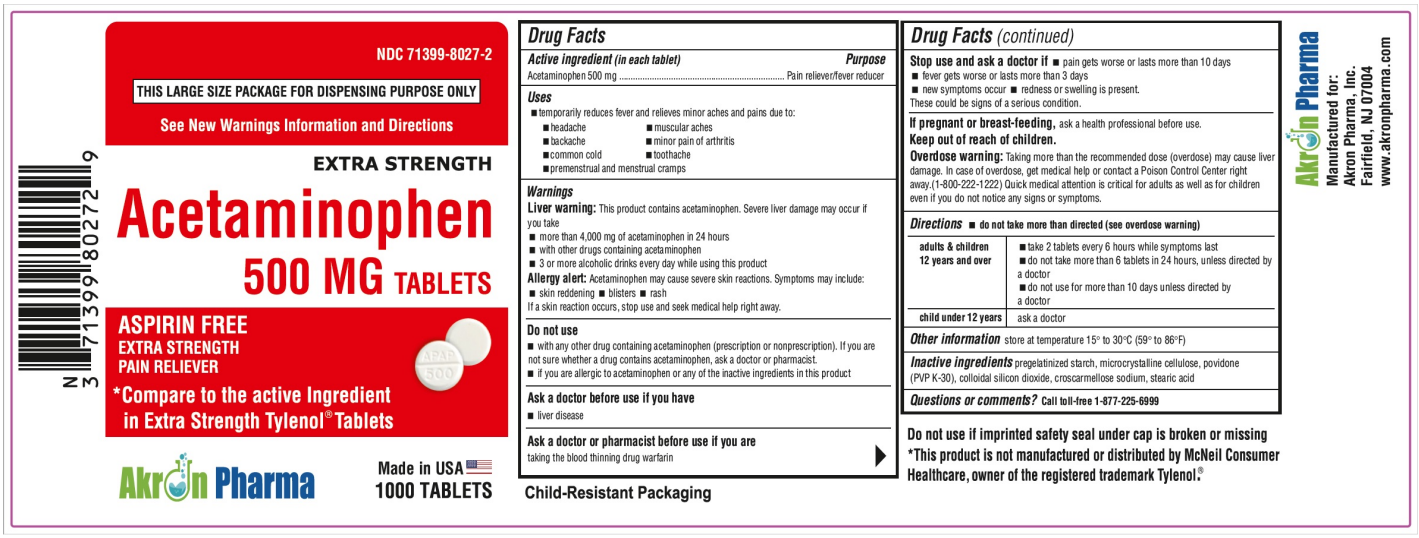
Call toll-free 1-877-225-6999

Manufactured for
Akron Pharma, Inc.,

373 RT US46 W Building E,

Suite 117, Fairfeld, NJ - 07004

* This product is not manufactured or distributed by McNeal Consumer Healthcare, Owner of registered trademark Tylenol.



ACETAMINOPHEN

acetaminophen extra strength tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-8027
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**

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	APAP500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8027-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2021	
2	NDC:71399-8027-2	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/05/2021	

Labeler - Akron Pharma Inc. (067878881)

Revised: 7/2021 Akron Pharma Inc.