

ADWE FEVERX ACETAMINOPHEN CAPLETS, 500 MG EXTRA STRENGTH- acetaminophen tablet

Aurex Laboratories Limited Liability Company

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.

Adwe Feverx Acetaminophen Caplets, 500 mg

Active Ingredient: Acetaminophen 500 mg

Uses:

- temporarily relieves minor aches and pains
- temporarily reduces fever

Minor aches and pains, fever.

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets in 24 hours. Severe liver damage may occur if you take:

- more than 8 caplets (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.

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.

Keep out of reach of children. 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.

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

Directions:

- **do not take more than directed**
- adults and children 12 years and over: take 1-2 caplets every 4-6 hours, as needed. Do not take more than 6 caplets in 24 hours, unless directed by a doctor.
- children under 12 years: ask a doctor

Other information

- Store at 20° C - 25° C (68° F - 77° F)

Inactive ingredients:

microcrystalline cellulose, vegetable magnesium stearate. May contain povidone.

* This product is not manufactured or distributed by the owner of the registered trademark **TYLENOL®**.

Distributed By:

Adwe Laboratories

1274 49 St. Brooklyn, NY 11219

This product contains no animal, soybean, or grain derivatives.

This product does not contain any Chometx or Krtnius.

REV 0221

ADWE FEVERX ACETAMINOPHEN CAPLETS, 500 MG EXTRA STRENGTH

ADWE FEVERX
Acetaminophen Caplets
EXTRA STRENGTH CAPLETS
Compare to the active ingredient in Extra Strength Tylenol®
PAIN RELIEVER • FEVER REDUCER
100 CAPLETS 500 mg each

NDC 71009-109-01

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TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.

Purposes
Acetaminophen 500 mg.....Pain Reliever / Fever Reducer

Drug Facts
Active ingredient (in each caplet)
Acetaminophen 500 mg.....Pain Reliever / Fever Reducer

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ADWE FEVERX ACETAMINOPHEN CAPLETS, 500 MG EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71009-109
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	A;A2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71009-109-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/09/2021	

Labeler - Aurex Laboratories Limited Liability Company (067585317)

Registrant - Adwe Products & Imports Inc. (080081765)

Establishment

Name	Address	ID/FEI	Business Operations
Aurex Laboratories Limited Liability Company		067585317	MANUFACTURE(71009-109)

Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceuticals, Corp		038883275	REPACK(71009-109)

Revised: 3/2021

Aurex Laboratories Limited Liability Company