

**ADWE FEVERX- acetaminophen tablet**  
**Syntho Pharmaceuticals, 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.*

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**ACETAMINOPHEN 500 MG TABLET**

***Drug Facts***

**Active ingredient (in each tablet)**

Acetaminophen 500 mg

**Purpose**

Pain Reliever/Fever Reducer

**Uses**

- temporarily relieves minor aches and pains
- temporarily reduces fever

**Warnings**

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

- more than 4,000 mg (8 tablets) in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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 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**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose get medical help or contact Poison Control Centre 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 & children 12 years and over:**

- take 1-2 tablets every 4-6 hours as needed
- do not take more than 6 tablets in 24 hours
- 

**children under 12 years: do not use**

**Other information**

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

- store at 20°C - 25°C (68°F - 77°F)

**Inactive ingredients**

povidone. May also contain: cellulose, croscarmellose sodium, magnesium silicate, silica, vegetable magnesium stearate

**Questions or comments**

\* This product is not manufactured or distributed by the owner of the registered trademark **TYLENOL®**. This product contains no animal, soybean or grain derivatives. This product does not contain any Chometz or Kitnius.

**☐ KOSHER FOR PASSOVER**

DIST BY: Adwe Laboratories

1274 49 St. Brooklyn, NY 11219

REV 201-0415

**☐ PRINCIPAL DISPLAY PANEL**

**NDC 666576-200-01**

**KOSHER FOR PASSOVER**

**Adwe Feverx**

**Acetaminophen Tablets**

**PAIN RELIEVER FEVER REDUCER**

**EXTRA STRENGTH TABLETS**

Compare to Active Ingredient in Extra Strength Tylenol®\*

100 TABLETS 500 mg each



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**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin.

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- new symptoms occur • redness or swelling is present

These could be signs of a serious condition.

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**Directions** • do not take more than directed

- adults and children 12 years and over: take 1-2 tablets every 4-6 hours, as needed; not more than 6 tablets in 24 hours
- children under 12 years: do not use

**Other information** • **TAMPER EVIDENT:** Do not use if imprinted seal under cap is missing or broken

- store at 20°C-25°C (68°F-77°F)

**Inactive ingredients:** povidone

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REV 201-0415 7 40168 20032 3

## ADWE FEVERX

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66576-200
<b>Route of Administration</b>	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
POVIDONE (UNII: FZ989GH94E)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66576-200-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/04/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/04/2020	

**Labeler** - Syntho Pharmaceuticals, Inc. (088797407)**Registrant** - Syntho Pharmaceuticals, Inc. (088797407)**Establishment**

Name	Address	ID/FEI	Business Operations
Syntho Pharmaceuticals, Inc.		088797407	manufacture(66576-200)

Revised: 2/2020

Syntho Pharmaceuticals, Inc.