

**ACETAMINOPHEN- acetaminophen tablet**  
**PD-Rx Pharmaceuticals, Inc.**

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**Drug Facts**

**Active Ingredient (in each tablet)**

Acetaminophen 500 mg

**Purpose**

Pain reliever/ Fever reducer

**Uses**

Temporarily reduces fever and relieves minor aches and pains due to:

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

**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.

- 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. (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 and children 12 years and over:**

- take 2 tablets every 6 hours while symptoms last
- do not take more than 6 tablets 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***

store at room temperature

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid

***Questions or comments?***

**Call 1-800-616-2471**



**TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.**

\*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Tylenol®.

**Acetaminophen Extra Strength Tablets**

Extra Strength Pain reliever

500mg each

<b>Drug Facts</b>		<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. <b>Overdose warning:</b> In the 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.</p> <p><b>Directions:</b> • Do not take more than directed (see overdose warning)</p> <table border="1"> <tr> <td>Adults and children 12 years and over</td> <td>• take 2 tablets every 6 hours while symptoms last • do not take more than 6 tablets in 24 hours, unless directed by a doctor • do not take for more than 10 days unless directed by a doctor</td> </tr> <tr> <td>Children under 12 years</td> <td>Ask a doctor</td> </tr> </table> <p><b>Other information:</b> Store at room temperature</p> <p><b>Inactive Ingredients:</b> Povidone, pregelatinized starch, sodium starch glycolate, stearic acid.</p> <p>Questions or comments? Call (800) 616-2471</p> <p><b>Marketed and Packaged By:</b> PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-(405) 942-3040 v.8.19.0</p> <p>    <b>GTIN:</b> 00372789241302  <b>SNO:</b> D22A99000005  <b>EXP:</b> 08/2023  <b>LOT:</b> D22A99 </p>	Adults and children 12 years and over	• take 2 tablets every 6 hours while symptoms last • do not take more than 6 tablets 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
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<p><b>Active Ingredient</b> (in each tablet) Acetaminophen 500mg..... Pain reliever/fever reducer</p> <p><b>Purpose</b> Pain reliever/fever reducer</p> <p><b>USES</b> • temporarily reduces fever and relieves minor aches and pains due to: • headache • muscular aches • common cold • toothache • backache • minor pain of arthritis • premenstrual and menstrual cramps</p> <p><b>Warnings</b> <b>Liver warning:</b> 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 <b>Allergy alert:</b> 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.</p> <p><b>Do not use</b> • 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.</p> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>Stop use and ask a doctor if:</b> 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.</p>	<p>NDC 72789-241-30</p> <p></p> <p><b>ACETAMINOPHEN</b></p> <p><b>Extra Strength</b></p> <p><b>500 mg</b></p> <p><b>30 Tablets</b></p> <p>TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>					

## ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72789-241(NDC:0904-6730)
<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
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	54;27
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:72789-241-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2022	
2	NDC:72789-241-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2022	
3	NDC:72789-241-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/12/2022	
4	NDC:72789-241-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2022	
5	NDC:72789-241-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/12/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/12/2018	

**Labeler** - PD-Rx Pharmaceuticals, Inc. (156893695)

**Registrant** - PD-Rx Pharmaceuticals, Inc. (156893695)

## Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(72789-241)

Revised: 7/2024

PD-Rx Pharmaceuticals, Inc.