

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

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**Acetaminophen Extra Strength Tablet**

***Drug Facts***

**Active ingredient (in each tablet)**

Acetaminophen 500 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**Warnings**

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

- more than 4000 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**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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 don't notice any signs or symptoms.

**Directions**

- **do not take more than directed (see overdose warning).**

adult and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 tablets, every 4 to 6 hours while symptoms last</li><li>• do not take more than 6 tablets in 24 hours, unless directed by a doctor</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	Ask a doctor

**Other information**

- store between 20-25 °C (68-77 °F)

**Inactive ingredients**

povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

**Questions or comments?**

(866)-562-2756 (Mon - Fri 8 AM to 4 PM EST)

## Acetaminophen 500mg

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

Drug Facts	
Active Ingredient	Purpose
(in each tablet) Acetaminophen 500mg.....	Pain reliever/fever reducer
<b>Uses</b>	
<ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to: • the common cold</li> <li>headache • backache • minor pain of arthritis • toothache • muscular aches • premenstrual and menstrual cramps • temporarily reduces fever</li> </ul>	
<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.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>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.</li> </ul>	
<b>Ask a doctor before use if you have liver disease.</b>	
<b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b>	
<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 • redness or swelling is present • new symptoms occur 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 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 don't 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 use for more than 10 days unless directed by a doctor
Children under 12 years	Ask a doctor

**Other information:** Store at 20-25°C (68-77°F)

**Inactive Ingredients:** Povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid.

**Questions or Comments?** (866) 562-2756 (Mon - Fri 8 AM to 4 PM EST)

**Marketed and Packaged By:**

PD-Rx Pharmaceuticals, Inc  
Oklahoma City, OK 73127  
1-405-942-3040 v.8.19.0

GTIN: 00355289880219  
SNO: L25G53000001  
EXP: 11/2027  
LOT: L25G53

NDC 55289-880-21



**ACETAMINOPHEN**  
**Extra**  
**Strength**  
**500 mg**

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

## ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55289-880(NDC:16103-376)
<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, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3S)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	PH044
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55289-880-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	
2	NDC:55289-880-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	
3	NDC:55289-880-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/09/2019	
4	NDC:55289-880-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
5	NDC:55289-880-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	
6	NDC:55289-880-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	
7	NDC:55289-880-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
8	NDC:55289-880-97	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	
9	NDC:55289-880-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2025	
10	NDC:55289-880-21	21 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/16/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/10/2006	

**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(55289-880)