

ACETAMINOPHEN- acetaminophen tablet
PD-Rx Pharmaceuticals, Inc.

Acetaminophen

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 ☐
- 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 (800) 616-2471

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®

16 HOW SUPPLIED/STORAGE AND HANDLING

Acetaminophen tablets, 500 mg are supplied as white, scored round tablets, debossed with "54;27".

In bottles of 20: (NDC 72789-241-20)

In bottles of 30: (NDC 72789-241-30)

In bottles of 50: (NDC 72789-241-50)



In bottles of 60: (NDC 72789-241-60)

In bottles of 100: (NDC 72789-241-01)

Acetaminophen Extra Strength Tablets

Extra Strength Pain reliever

500mg each

Drug Facts Active Ingredient Purpose (in each tablet) Acetaminophen 500mg..... Pain reliever/fever reducer		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 do not notice any signs or symptoms.	NDC 72789-241-30  ACETAMINOPHEN Extra Strength 500 mg
USES • 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			
Warnings 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.		Directions: • Do not take more than directed (see overdose warning) • 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	30 Tablets TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.
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 you are allergic to acetaminophen or any of the inactive ingredients in this product.		Other information: Store at room temperature Inactive Ingredients: Povidone, pregelatinized starch, sodium starch glycolate, stearic acid. Questions or comments? Call (800) 616-2471	
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.		Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-(405) 942-3040 v.8.19.0	3 72789 24130 2 
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.		GTIN: 00372789241302 SNO: D22A99000005 EXP: 08/2023 LOT: D22A99	

ACETAMINOPHEN

acetaminophen tablet

Product Information

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

Product Characteristics

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

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:72789-241-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2022	
4	NDC:72789-241-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/12/2022	
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: 10/2023

PD-Rx Pharmaceuticals, Inc.