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 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 8 tablets in 24 hours, which is the maximum daily amount
- 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 the case of overdose, get medical help or contact a Poison Control Center right away.(1-800-222-1222).

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

adult and children 12 years and over	• take 2 tablets, every 4 to 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 between 20-25 ^{0}C (68-77 ^{0}F)

Inactive ingredients

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

Questions or comments?

Adverse drug event call: (866) 562-2756 Mon-Fri 8AM to 4PM

Acetaminophen 500mg

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

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55289-880(NDC:16103-376)
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**
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	PH044
Contains			

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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	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)

Revised: 3/2024 PD-Rx Pharmaceuticals, Inc.