ACETAMINOPHEN REGULAR STRENGTH- acetaminophen tablet
PD-Rx Pharmaceuticals, Inc.

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325mg

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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children.

Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 the 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).

adults and children 12 years and over	• take 2 tablets, every 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directe by a doctor • do not use for more than 10 days unless directed by a doctor
children 6 to under 12 years	• take 1 tablet every 4 to 6 hours while symptoms last • do not take more than 5 tablets in 24 hours • do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

- **Tamper Evident: do not use if seal is broken or missingfrom bottle.**

- store between 20-25°C (68-77°F)

Inactive ingredients

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

Questions?

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

16 HOW SUPPLIED/STORAGE AND HANDLING

Acetaminophen tablets, 325 mg are supplied as white, round tablets, debossed with “PH020”.

In bottles of 4: (NDC 55289-563-04)

In bottles of 6: (NDC 55289-563-06)

In bottles of 9: (NDC 55289-563-09)

In bottles of 12: (NDC 55289-563-12)

In bottles of 16: (NDC 55289-563-16)

In bottles of 20: (NDC 55289-563-20)

In bottles of 24: (NDC 55289-563-24)

In bottles of 30: (NDC 55289-563-30)

In bottles of 50: (NDC 55289-563-50)

In bottles of 100: (NDC 55289-563-01)

Acetaminophen 325mg each

ACETAMINOPHEN REGULAR STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55289-563(NDC:16103-353)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	PH020
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55289-563-04	4 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
2	NDC:55289-563-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
3	NDC:55289-563-09	9 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
4	NDC:55289-563-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
5	NDC:55289-563-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
6	NDC:55289-563-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
7	NDC:55289-563-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
8	NDC:55289-563-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
9	NDC:55289-563-16	16 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/09/2007	

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(55289-563)

Revised: 12/2023 PD-Rx Pharmaceuticals, Inc.