

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	<ul style="list-style-type: none">• take 2 tablets, every 4 to 6 hours while symptoms last• do not take more than 10 tablets in 24 hours, unless directed by a doctor• do not use for more than 10 days unless directed by a doctor
children 6 to under 12 years	<ul style="list-style-type: none">• 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 missing from 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 9: (NDC 55289-563-09)

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

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

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

Acetaminophen 325mg each

<p>Drug Facts</p> <p>Active Ingredient Purpose</p> <p>(in each tablet) Acetaminophen 325mg Pain reliever/fever reducer</p> <p>USES</p> <p>• 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</p> <p>Warnings</p> <p>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.</p> <p>Allergy alert: Acetaminophen may cause severe skin reaction. symptoms may include: • skin reddening • blisters • rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <p>• 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>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.</p> <p>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 reach of children. Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In the case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Directions:</p> <p>• Do not take more than directed (see dose warning).</p> <table border="1"> <tr> <td>Adults and children 12 years and over</td> <td>• take 2 tablets every 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directed by a doctor • do not use for more than 10 days unless directed by a doctor</td> </tr> <tr> <td>Children 6 to 11 years</td> <td>• 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</td> </tr> <tr> <td>Children under 6 years</td> <td>Ask a doctor</td> </tr> </table>		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 directed by a doctor • do not use for more than 10 days unless directed by a doctor	Children 6 to 11 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
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<p>Other information: Store between 20-25°C (68-77°F)</p> <p>Inactive Ingredients Povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid.</p> <p>Questions? Adverse drug event call (866) 562-2756 Mon - Fri 8 AM to 4 PM</p>		<p>NDC 55289-563-30</p> <p>ACETAMINOPHEN</p> <p>325 mg</p> <p>3 55289 56330 3</p> <p>Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040 v.8.19.0</p> <p>30 Tablets</p> <p>TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>							
<p>GTIN: 00355289563303</p> <p>SNO: I20D110002</p> <p>EXP: 09/2022</p> <p>LOT: I20D11</p>									

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:55289-563-09	9 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
2	NDC:55289-563-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	
3	NDC:55289-563-16	16 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2023	
4	NDC:55289-563-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2017	

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: 6/2024

PD-Rx Pharmaceuticals, Inc.