

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

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**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"><li>• take 2 tablets, every 4 to 6 hours while symptoms last</li><li>• do not take more than 10 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 6 to under 12 years          | <ul style="list-style-type: none"><li>• take 1 tablet every 4 to 6 hours while symptoms last</li><li>• do not take more than 5 tablets in 24 hours</li><li>• do not use for more than 5 days unless directed by a doctor</li></ul>                                  |
| 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)

## Acetaminophen 325mg each

|   |  |  |   |  |                        |  |                        |              |  |
|---|--|--|---|--|------------------------|--|------------------------|--------------|--|
| <b>Drug Facts</b><br><b>Active Ingredient</b> <b>Purpose</b><br>(in each tablet)<br>Acetaminophen 325mg      Pain reliever/fever reducer  |  | <b>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.</b><br><b>Stop use and ask a doctor if:</b> 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.<br><b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning:</b> 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). | <b>NDC 55289-563-30</b><br><br><br><b>ACETAMINOPHEN</b><br><b>325 mg</b><br><br><br><b>3 55289 56330 3</b><br><br><b>Marketed and Packaged By:</b><br>PD-Rx Pharmaceuticals, Inc<br>Oklahoma City, OK 73127<br>1-405-942-3040 v.8.19.0 |  |                        |  |                        |              |  |
| <b>USES</b><br>• 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<br><br><b>Warnings</b><br><b>Liver warning:</b> 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.<br><b>Allergy alert:</b> 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.<br><b>Do not use</b><br>• 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. |  |  |   | <b>Directions:</b><br><b>• Do not take more than directed (see ove dose warning).</b>  |                        |  |                        |              |  |
|  <b>GTIN: 00355289563303</b><br><b>SNO: I20D110002</b><br><b>EXP: 09/2022</b><br><b>LOT: I20D11</b>   |  | <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 | <b>30 Tablets</b><br><b>TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.</b> |
| 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   |  |   |  |                        |  |                        |              |  |
| <b>Other information:</b> Store between 20-25°C (68-77°F)<br><b>Inactive Ingredients:</b> Povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid.<br><b>Questions? Adverse drug event call (866) 562-2756 Mon - Fri 8 AM to 4 PM</b>   |  |  |   |  |                        |  |                        |              |  |

## ACETAMINOPHEN REGULAR STRENGTH

acetaminophen tablet

### Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55289-563(NDC:16103-353) |
| <b>Route of Administration</b> | 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 |
|---|----------|
| <b>POVIDONE</b> (UNII: FZ989GH94E)                            |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                        |          |
| <b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B) |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                        |          |

### Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | white | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND | <b>Size</b>         | 10mm     |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | PH020    |
| <b>Contains</b> |       |                     |          |

### 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:55289-563-16 | 16 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/12/2023           |                    |
| 3 | NDC:55289-563-24 | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/13/2017           |                    |
| 4 | NDC:55289-563-30 | 30 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: 3/2025

PD-Rx Pharmaceuticals, Inc.