**ADULT LOW DOSE ASPIRIN- aspirin tablet, delayed release**
**PD-Rx Pharmaceuticals, Inc.**

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## Drug Facts

### Active ingredient (in each tablet)

Aspirin 81mg (NSAID)*

*nonsteroidal anti-inflammatory drug

### Purpose

Pain Reliever

### Uses

- for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product may not provide fast relief of headache or other symptoms needing immediate relief.
- ask your doctor about other uses for this product

### Warnings

**Reye's syndrome:**Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:**Aspirin may cause a severe allergic reaction which may include:

- hives
- asthma (wheezing)
- facial swelling
- shock

**Stomach bleeding warning:**This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

### Do not use

if you have ever had an allergic reaction to aspirin or any other pain reliever/fever

reducer

**Ask a doctor before use if**

- the stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are taking a prescription drug for:**

- gout
- diabetes
- arthritis

**Stop use and ask a doctor if:**

- you experience any of the following signs of stomach bleeding • feel faint •vomit blood •have bloody or black stools •have stomach pain that does not get better
- allergic reaction occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours while symptoms persist. Do not to exceed 48 tablets in 24 hours or as directed by a physician
- children under 12 years: consult a physician

**Other information**

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store at room temperature (15°-30°C)
- avoid excess heat and moisture

## Inactive ingredients

croscarmellose sodium, D&C yellow# 10 lake, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide.

## Questions? Adverse drug event call:

(866) 562-2756

## HOW SUPPLIED

Round yellow delayed release tablet imprinted with PH023 is supplied in:

Bottles of 35 NDC 72789-039-35

Bottles of 100 NDC 72789-039-01

Bottles of 120 NDC 72789-039-98

**Aspirin**


## ADULT LOW DOSE ASPIRIN

aspirin tablet, delayed release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72789-039(NDC:16103-356) |

| | |
|---|---|
| **Route of Administration** | ORAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 81 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2)** (UNII: XRK36F13ZZ) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow (YELLOW COLOR) | **Score** | no score |
| **Shape** | ROUND (ROUND TABLET) | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | PH023 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:72789-039-98 | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/20/2019 | |
| **2** | NDC:72789-039-01 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/21/2020 | |
| **3** | NDC:72789-039-35 | 35 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/21/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M013 | 01/12/2007 | |

## 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(72789-039) |

Revised: 10/2023

PD-Rx Pharmaceuticals, Inc.