**IBUPROFEN- ibuprofen tablet, film coated**
**PD-Rx Pharmaceuticals, Inc.**

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**IBUPROFEN 800 MG TABLETS**

**ibuprofen tablets 400 mg - 600 mg- 800 mg medguide**

800 mg (white to off-white, capsule shaped, biconvex, film-coated tablets debossed with ‘123’ on one side and plain on other side)

Bottles of 4, 6, 9, 10, 12, 15, 18, 20, 21, 24, 28, 30, 40, 60, 90, 100, 180, 270 and 500.

**800 mg label**


# IBUPROFEN

ibuprofen tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:43063-858(NDC:49483-604) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **IBUPROFEN** (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 800 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **POLYVINYL ALCOHOL** (UNII: 532B59J990) | |
| **STARCH, PREGELATINIZED CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | 123 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:43063-858-04 | 4 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/22/2018 | |
| **2** | NDC:43063-858-06 | 6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/04/2019 | |
| **3** | NDC:43063-858-09 | 9 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/20/2019 | |
| **4** | NDC:43063-858-10 | 10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/06/2018 | |
| **5** | NDC:43063-858-12 | 12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **6** | NDC:43063-858-15 | 15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **7** | NDC:43063-858-18 | 18 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **8** | NDC:43063-858-20 | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/21/2018 | |
| **9** | NDC:43063-858-21 | 21 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2018 | |
| **10** | NDC:43063-858-24 | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/08/2019 | |
| **11** | NDC:43063-858-28 | 28 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2019 | |
| **12** | NDC:43063-858-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **13** | NDC:43063-858-40 | 40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/03/2018 | |
| **14** | NDC:43063-858-60 | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **15** | NDC:43063-858-82 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/24/2020 | |
| **16** | NDC:43063-858-90 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **17** | NDC:43063-858-01 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/03/2019 | |
| **18** | NDC:43063-858-93 | 180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |
| **19** | NDC:43063-858-94 | 270 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/08/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA090796 | 12/30/2015 | |

## 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(43063-858) |

Revised: 3/2020 PD-Rx Pharmaceuticals, Inc.