**IBUPROFEN- ibuprofen tablet**
**Kinray, Inc.**

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**Drug Facts**

**Active ingredient (in each tablet)**

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti- inflammatory drug

**Purpose**

Pain Reliever/ Fever Reducer

**Uses**

temporarily relieves minor aches and pain due to:

- headache
- toothache
- backache
- menstrual cramps
- the common cold
- muscular aches
- minor pain of arthritis
- temporarily reduces fever

**Warnings**

**Allergy alert:**

Ibuprofen may cause a severe allergic reaction, especially in people allergic to Aspirin. Symptoms may include

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**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 non prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday 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 any other pain reliever/ fever reducer
- right before or after heart surgery

**Ask a doctor before use if**
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**
- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

**when using this product**
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

**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
- pain gets worse or last for more than 10 days
- fever gets worse or last more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast feeding,**

ask a health professional before use. It is especially important not to use ibuprofen 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 overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**

| | |
|---|---|
| adults and children 12 years and older | • take 1 tablet every 4 to 6 hours while symptoms persist<br>• if pain or fever does not respond to 1 tablet, 2 tablets may be used<br>• do not exceed 6 tablets in 24 hours, unless directed by a doctor |
| children under 12 years | • consult a doctor |

**Other information**

- **Tamper Evident: do not use if safety seal under cap is broken or missing**
- store at room temperature (20°- 25°C)
- avoid excessive heat above 40°C (104°F)

**Inactive Ingredients:**

colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, red iron oxide, talc & titanium dioxide

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

*This product is not manufactured or distributed by Pfizer Consumer Products, owner of the registered trademark ADVIL®.

NDC 61715-167-50

*Compare to the active ingredient in Advil®

Preferred plus Pharmacy

Pain Reliever / Fever Reducer (NSAID)

IBUPROFEN Tablets

200mg

50 Tablets


# IBUPROFEN

ibuprofen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61715-167 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **IBUPROFEN** (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL 3350** (UNII: G2M7P15E5P) | |
| **POLYVINYL ALCOHOL** (UNII: 532B59J990) | |
| **STARCH, PREGELATINIZED CORN** (UNII: O8232NY3SJ) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 114 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61715-167-50 | 1 in 1 CARTON | | |
| **1** | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:61715-167-51 | 1 in 1 CARTON | | |
| **2** | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA091239 | 03/01/2016 | |

## Labeler - Kinray, Inc. (012574513)

## Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Pharbest Pharmaceuticals, Inc. | | 557054835 | repack(61715-167) , relabel(61715-167) |

Revised: 3/2016 Kinray, Inc.