**IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER- ibuprofen tablet**
**Amneal Pharmaceuticals of New York LLC**

---

**Ibuprofen Caplets, USP**
**Fever reducer/ Pain Reliever (NSAID)**

## *Drug Facts*

### *Active ingredient*

### *(in each caplet)*

Ibuprofen USP, 200 mg (NSAID)**

**nonsteroidal anti-inflammatory drug

### *Purpose*

Pain reliever/fever reducer

### *Uses*

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- 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 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

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- you have problems or serious side effects from taking pain relievers or fever reducers
- 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, kidney disease, asthma, or had a stroke
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs

**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
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts 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 at 20 weeks or later in 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**

**Keep out of reach of children**. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

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

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

**Other information**

- read all warnings and directions before use
- store between 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

- Brown Caplets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, Hypromellose, Iron Oxide Red, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide

- Orange Caplets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, FD&C Yellow #6, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide

**Questions or Comments?**

Call 1-877-835-5472

Monday through Friday 9AM - 5PM EST.

*Amneal Pharmaceuticals is not affiliated with the owner of the trademark Advil®

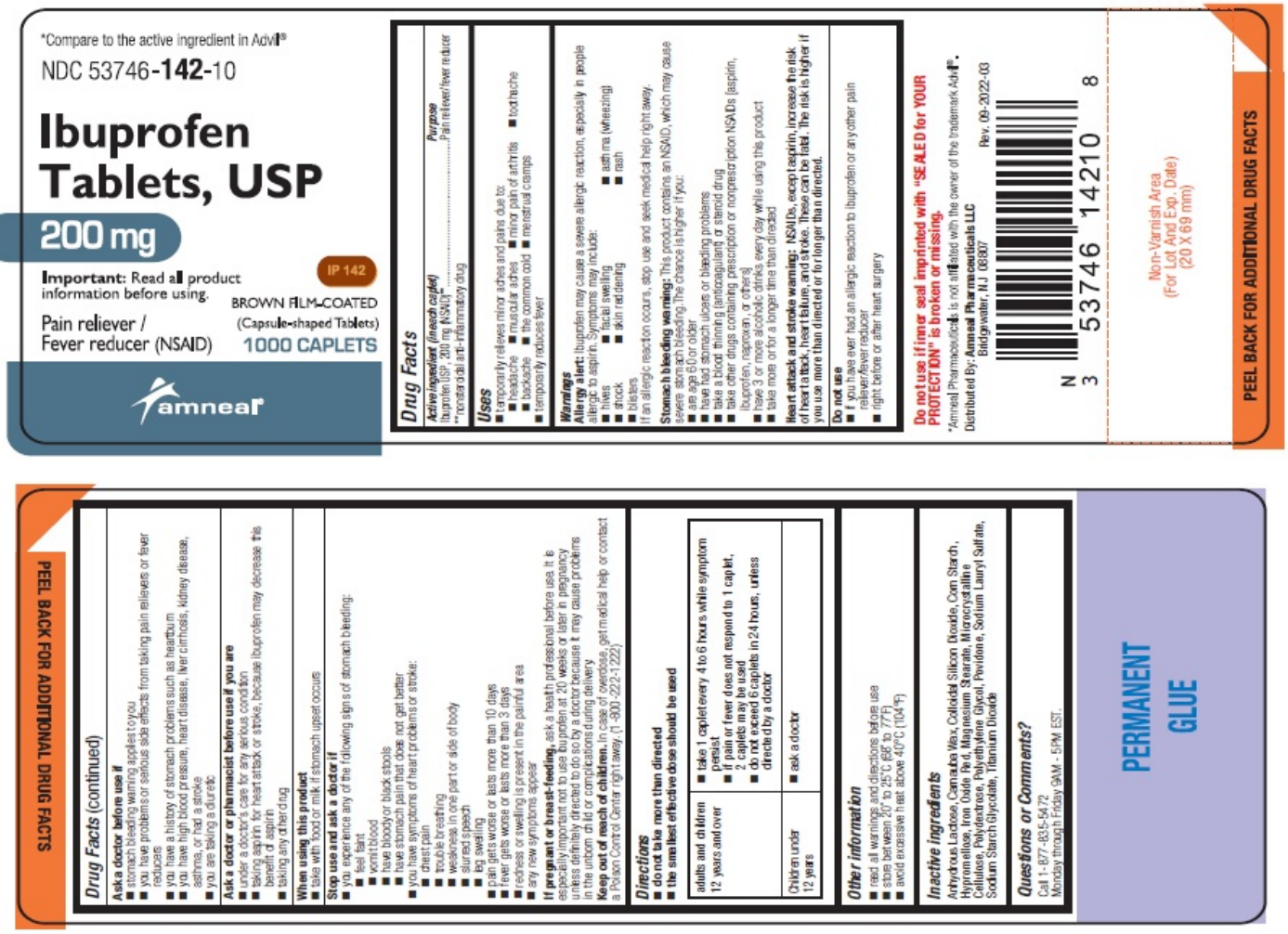
Distributed By:

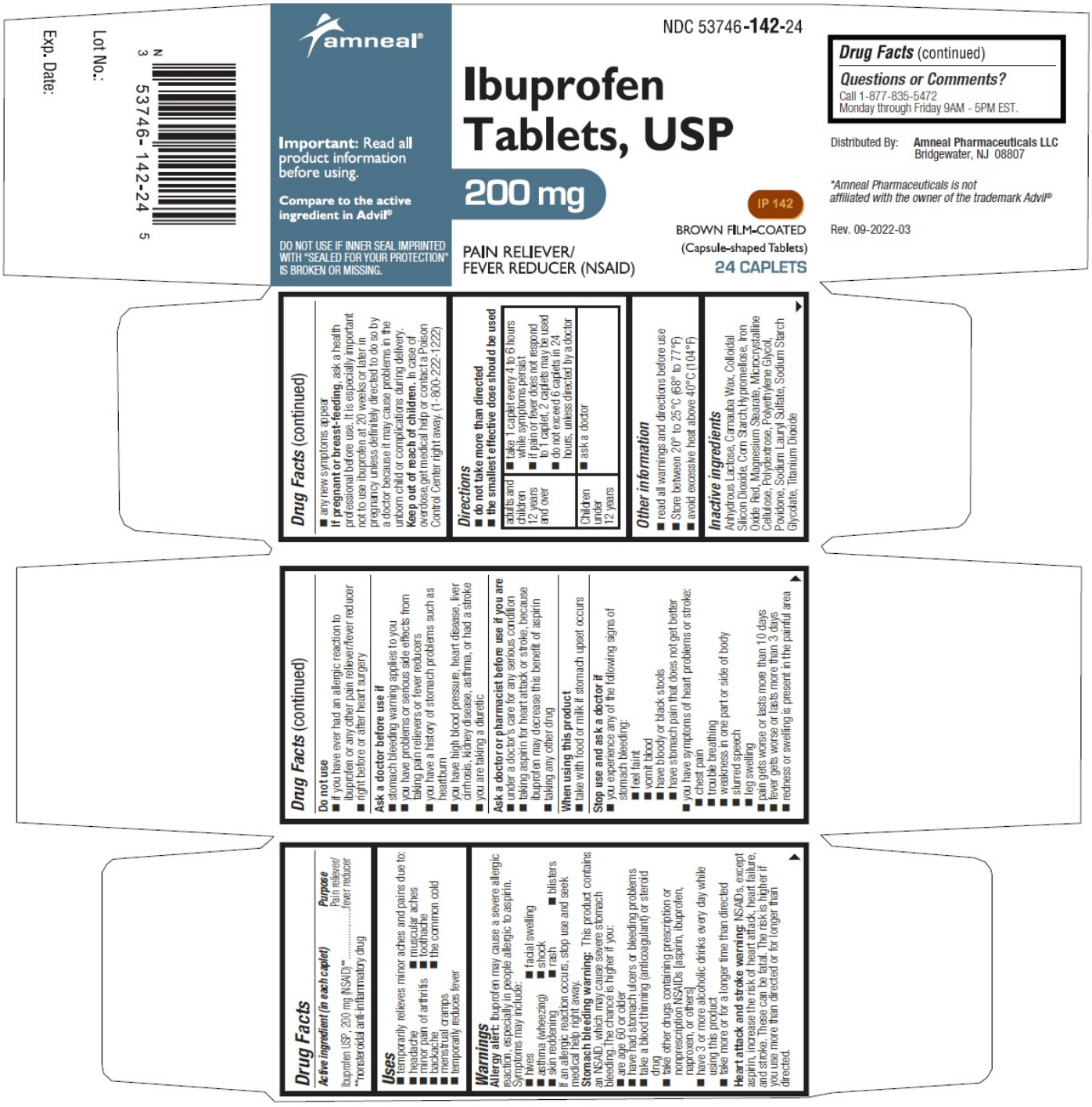
**Amneal Pharmaceuticals LLC**

Bridgewater, NJ 08807

Rev. 09-2022-02

## PACKAGE LABEL PRINCIPAL DISPLAY PANEL






**PACKAGE LABEL PRINCIPAL DISPLAY PANEL**

*Compare to the active ingredient in Motrin IB®

NDC 53746-144-10

# Ibuprofen Tablets, USP

## 200 mg

IP 144

**Important:** Read all product information before using.

ORANGE FILM-COATED (Capsule-shaped Tablets)

Pain reliever / Fever reducer (NSAID)

1000 CAPLETS

amneal

## Drug Facts

| *Active ingredient (in each caplet)* | *Purpose* |
|---|---|
| Ibuprofen USP, 200 mg (NSAID)** | Pain reliever/fever reducer |

**nonsteroidal anti-inflammatory drug

### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- 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 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

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

**Do not use if inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

**Amneal Pharmaceuticals is not affiliated with the owner of the trademark Motrin IB®*

Distributed By: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 09-2022-03

N 3 53746 14410 2

Non-Varnish Area
(For Lot And Exp. Date)
(20 X 69 mm)

**PEEL BACK FOR ADDITIONAL DRUG FACTS**

**PEEL BACK FOR ADDITIONAL DRUG FACTS**

## Drug Facts (continued)

**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, asthma, or had a stroke
- 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

**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
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts 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 at 20 weeks or later in 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 over | ■ take 1 caplet every 4 to 6 hours while symptoms persist<br>■ if pain or fever does not respond to 1 caplet, 2 caplets may be used<br>■ do not exceed 6 caplets in 24 hours, unless directed by a doctor |
| Children under 12 years | ■ ask a doctor |

### Other information

- read all warnings and directions before use
- store between 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

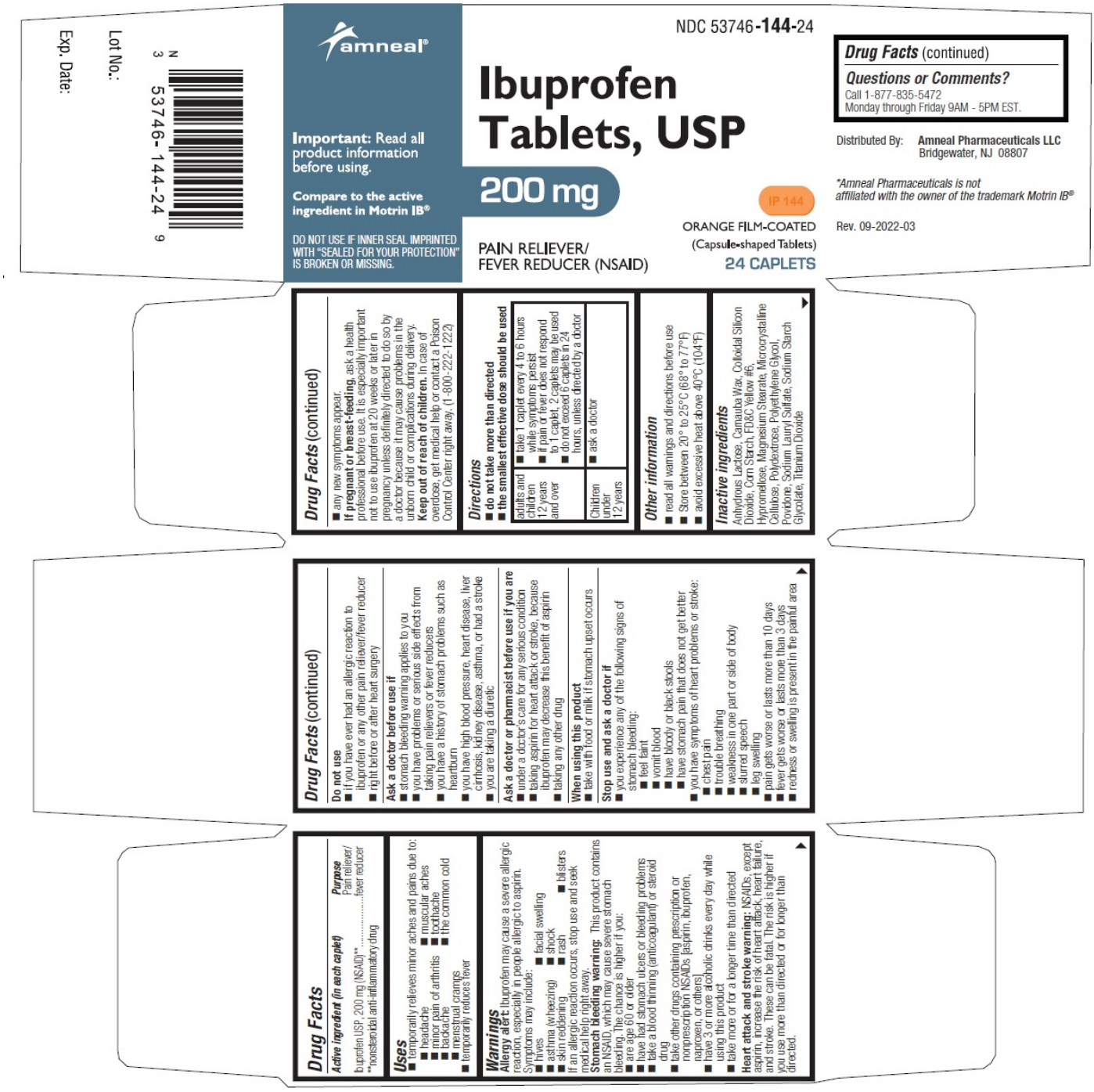
### Inactive ingredients

Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, FD&C Yellow #6, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide

### Questions or Comments?

Call 1-877-835-5472
Monday through Friday 9AM - 5PM EST.

PERMANENT GLUE




# IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER

ibuprofen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:53746-144 |
| **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 |
|---|---|
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | IP;144 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:53746-144-24 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2009 | |
| **2** | NDC:53746-144-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2009 | |
| **3** | NDC:53746-144-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2009 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA072199 | 12/16/2009 | |

# IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER

ibuprofen tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:53746-142 |
| **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 |
|---|---|
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | IP;142 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:53746-142-24 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2009 | |
| **2** | NDC:53746-142-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2009 | |
| **3** | NDC:53746-142-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2009 | |

# Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA072199 | 12/16/2009 | |

**Labeler -** Amneal Pharmaceuticals of New York LLC (123797875)

Revised: 12/2023 Amneal Pharmaceuticals of New York LLC