# SLATE RUN PHARMACEUTICALS

# IBUPROFEN TABLETS, USP



To most, "generics" means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.



## PRODUCT DETAILS

- Strength: Available in 400 mg, 600 mg, and 800 mg Tablets
- · Therapeutic Class: NSAID

#### **NDC Numbers:**

400 mg | Bottle of 100: **70436-180-01** 400 mg | Bottle of 500: **70436-180-02** 600 mg | Bottle of 100: **70436-181-01** 600 mg | Bottle of 500: **70436-081-02** 800 mg | Bottle of 100: **70436-082-01** 800 mg | Bottle of 500: **70436-082-02** 

To place an order or learn more, call **844-529-8988 (Toll Free)** or email

#### sales@slaterunpharma.com

6am – 7pm CST (Monday - Friday) Available through your wholesaler:

NDC: 70436-180-01

Cardinal Health: 5799721 McKesson: 2634327 Amerisource: 10271503

NDC: 70436-180-02

Cardinal Health: 5799739 McKesson: 2634335 Amerisource: 10271504

NDC: 70436-181-01

Cardinal Health: 5799747 McKesson: 2634343 Amerisource: 10271505

NDC: 70436-181-02

Cardinal Health: 5799754 McKesson: 2634350 Amerisource: 10271496

NDC: 70436-182-01

Cardinal Health: 5799762 McKesson: 2634368 Amerisource: 10271497

NDC: 70436-182-02

Cardinal Health: 5799770 McKesson: 2634376 Amerisource: 10271495

### IMPORTANT SAFETY INFORMATION FOR:

# **IBUPROFEN TABLETS, USP**

#### **WARNING: Cardiovascular Thrombotic Events**

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- · Ibuprofen Tablets are contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

#### **WARNING: Gastrointestinal Risk**

 NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

#### Ibuprofen Tablets, USP are contraindicated:

- · In patients with known hypersensitivity to ibuprofen.
- In patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.
- · In the setting of coronary artery bypass graft.

NSAIDs including ibuprofen tablets, can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of cardiovascular events. NSAIDs, including ibuprofen tablets, should be used with caution in patients with hypertension. Blood pressure should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.

Avoid the use of ibuprofen tablets in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ibuprofen tablets are used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

NSAIDs, including ibuprofen tablets, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin reaction or any other sign of hypersensitivity.

The most common adverse reactions include nausea, epigastric pain, heartburn, dizziness, and rash. Please see the package insert for Ibuprofen Tablets, USP for full prescribing information.