**IBUTAB- ibuprofen tablet**
**Zee Medical Inc**

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**Drug Facts**

Active Ingredient/Tablet Ibuprofen 200 mg (NSAID*) *nonsteroidal anti-inflammatory drug

Purpose-Pain Reliever/Fever Reducer

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

Directions
- do not take more than directed
- the smallest effective dose should be used
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- adults: take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours
- children under 12 years: ask a doctor

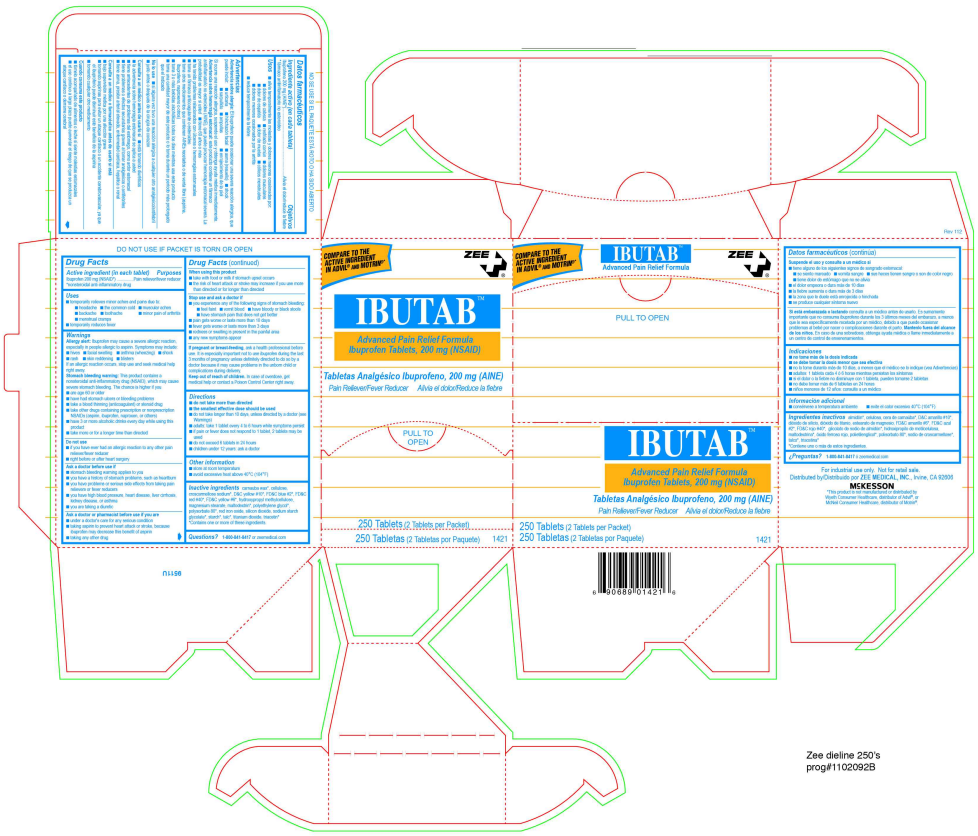
Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ hives ■ facial swelling ■ asthma (wheezing) ■ shock
■ rash ■ skin reddening ■ blisters
If an allergic reaction occurs, stop use and seek medical help right away.
Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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 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 a history of stomach problems, such as heartburn
■ you have problems or serious side effects from taking pain relievers or fever reducers
■ 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 to prevent 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 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 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Inactive ingredients carnauba wax*, cellulose, croscarmellose sodium*, DC yellow 10*, FDC blue 2*, FDC red 40*, FDC yellow 6*, hydroxypropyl methylcellulose, magnesium stearate, maltodextrin*, polyethylene glycol*, polysorbate 80*, red iron oxide, silicon dioxide, sodium starch glycolate*, starch*, talc*, titanium dioxide, triacetin*
*Contains one or more of these ingredients.




# IBUTAB

ibuprofen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:35418-750 |
| **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** |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| | |
|---|---|
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **POLYETHYLENE GLYCOL 300** (UNII: 5655G9Y8AQ) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown (chocolate brown) | **Score** | no score |
| **Shape** | ROUND (IBU;200) | **Size** | 110mm |
| **Flavor** | | **Imprint Code** | IBU;200 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:35418-750-69 | 500 in 1 CARTON | 06/12/2012 | |
| **1** | NDC:35418-750-67 | 125 in 1 CARTON | | |
| **1** | NDC:35418-750-68 | 50 in 1 CARTON | | |
| **1** | NDC:35418-750-02 | 2 in 1 PACKET; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA079129 | 06/12/2012 | |

## Labeler - Zee Medical Inc (009645623)

## Registrant - Ultra Seal Corporation (085752004)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Ultra Seal Corporation | | 085752004 | pack(35418-750) |

Revised: 10/2019 Zee Medical Inc