

PATIENT INFORMATION LEAFLET

IBU-BABY 60 mg suppository **For rectal use.**

- **Active substance:** Each suppository contains 60 mg ibuprofen.
- **Excipient(s):** Witepsol H5, polysorbate 80.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET**. You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher or lower** doses other than what is recommended to you.*

What is in this leaflet:

- 1. What is IBU-BABY and what is it used for?**
- 2. Before you use IBU-BABY**
- 3. How to use IBU-BABY?**
- 4. Possible side effects**
- 5. How to store IBU-BABY?**

1. What is IBU-BABY and what is it used for?

- IBU-BABY is an almost white, uniform suppository.
- IBU-BABY is available in a cardboard boxes containing 6 and 10 suppositories.
- Each suppository contains 60 mg active substance (ibuprofen). Ibuprofen is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- IBU-BABY is used for the reduction of fever and relief of mild to moderate pain (such as teething pain, toothache, earache, headache of known origin, mild muscle pain, sore throat, pain associated with sprains and strains).
- When IBU-BABY is administered rectally, absorption is less than oral use. Therefore, it is only used as an effective alternative if oral use is not possible or if vomiting occurs.

2. Before you use IBU-BABY

DO NOT use IBU-BABY in the following conditions

If;

- You are allergic to ibuprofen or non-steroidal anti-inflammatory/analgesic medicines or any of the ingredients that this medicine contains
- You have experienced bronchial constriction, asthma attack, swelling in the nasal mucosa, skin reactions (swelling of the face, lips, tongue and throat) after taking ibuprofen, aspirin or other non-steroidal anti-inflammatory (NSAID) medicines

- You have suffered in the past from gastrointestinal bleeding or perforation associated with previous treatment with NSAIDs
- You suffer or have suffered in the past from recurring gastric-duodenal ulcers, inflammatory bowel diseases (ulcerative colitis, Crohn's disease), gastrointestinal bleeding
- You have increased bleeding tendency (if there are conditions causing easy bleeding)
- You have severe liver impairment
- You have kidney impairment
- You have heart failure (NYHA Class IV)
- You are in the last three months of pregnancy
- You are in the period before or after coronary artery by-pass surgery (surgery to treat the blockage in coronary arteries)
- Your child's body weight is less than 6 kg and he/she is less than 6 months old

USE IBU-BABY with CAUTION

Cardiovascular (CV) Risk

- NSAIDs may be associated with increased risk of cardiovascular thrombotic events (related to clotting), myocardial infarction and stroke, which can be fatal. This risk may increase with prolonged duration of treatment. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

- IBU-BABY is contraindicated for treatment of pain prior to coronary artery by-pass surgery.

Gastrointestinal (GI) risks

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 adverse events can occur at any time with or without prior warning symptoms. Elderly patients are at a greater risk for serious gastrointestinal events.

Transition of rectally administered ibuprofen to blood may be less predictable than oral administration.

There is a risk of rectal perforation during administration.

- If you have a disease caused by malfunction of the immune system such as systemic lupus erythematosus (a disease of unknown origin characterized by symptoms related to inflammation of many tissues and organs such as skin, joint, kidney, pericardium, pleura, that shows different course and caused by malfunction of the immune system) and mixed connective tissue disease
- If you experience chill, tremor and sudden increase in fever, loss of sense of direction, fatigue, headache, nausea and vomiting or neck stiffness; immediately consult your doctor. These may be symptoms of a type of inflammation of the meninges (aseptic meningitis)
- If you have gastrointestinal disorder, chronic inflammatory bowel disease (ulcerative colitis, Crohn's disease), rectal or anal disorders
- If you have high blood pressure and/or heart failure

- If you have suffered in the past from gastrointestinal bleeding or perforation associated with previous treatment with ibuprofen
- If you have liver impairment
- If you suffer or have suffered in the past from allergic asthma, chronic (long-standing) rhinitis, sinusitis, nasal polyp or allergic disease
- Sufficient amount of fluid intake is essential in case of fluid loss. For example, special attention should be paid to children with severe fluid loss due to diarrhea, otherwise fluid loss may lead to sudden kidney failure
- If you have kidney, heart, intestinal and liver disease
- If you have high blood pressure, heart failure, angina (chest pain) or you have had a previous heart attack, by-pass surgery (surgery to treat the blockage in coronary arteries), peripheral vascular disease (poor circulation in legs or feet due to narrowed or blocked veins) or stroke (including transient ischemic attack)
- If you use other non-steroidal anti-inflammatory drugs (NSAIDs) or painkillers, consult your doctor before using
- Take special care in elderly especially as there is a greater risk of serious side effects such as bleeding and perforation or ulceration in the gastrointestinal tract, which can be fatal
- If you experience an inflammation with blood blister, swelling and redness on the skin and around the eyes (Stevens-Johnson syndrome), a severe disease with water blister on the skin, peeling skin and loss of tissue (toxic epidermal necrosis) or hypersensitivity reaction (erythema multiforme) which generally resolves spontaneously and produces lacy redness on the face, hand and feet, stop using the medicine and consult a doctor
- If you are in the first 6 months of your pregnancy
- Anemia is sometimes seen in patients receiving non-steroidal anti-inflammatory drugs (NSAIDs), including IBU-BABY. Patients who have been treated for a long time with non-steroidal anti-inflammatory drugs (NSAIDs), including ibuprofen, should have checked the blood levels (hemoglobin and hematocrit) levels if signs or symptoms of anemia occur
- Inform your doctor if you are taking anticoagulant medication
- If unexplained weight gain and water retention (edema) occur
- If you see blood in your vomit or you have bloody or black stool, stop using the medicine and consult a doctor. Prolonged use of ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs) is associated with ulcers, bleeding and perforation of the gastrointestinal tract even though this type of disease has not previously been experienced. The risk of the occurrence of such undesirable effects increases in those who have suffered in the past from such a disease, in the elderly, at high doses and when the duration of treatment is prolonged
- If there is severe fluid loss due to diarrhea or other reasons

Please consult your doctor, even if these warnings apply to you at any time in the past.

Using IBU-BABY with food and drink

It is not applicable due to its method of administration

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

IBU-BABY should only be used on a doctor's recommendation in the first and second trimester of pregnancy. In the last three months of pregnancy, IBU-BABY should not be used because of the problems for the mother and her baby.

There is no information on the effect on birth control methods. It is recommended that you use or continue to use effective birth control methods throughout your treatment if you are not planning to become pregnant, although it is known that the use of ibuprofen may have a negative effect on fertility.

Occasional use of ibuprofen is not expected to affect your chances of getting pregnant, but if you have problems with conceiving, inform your doctor before using this medicine.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Breast-feeding

Before using this medicine consult your doctor or pharmacist.

It is not known whether the medicine passes into breast milk. Because many medicines are secreted into breast milk and IBU-BABY has a serious side-effect potential if newborns are breastfed, your doctor may decide to stop breastfeeding or use of medication by taking into account the importance of drug use.

Driving and using machinery

IBU-BABY can cause side effects such as drowsiness, lethargy, fatigue, and visual disturbances. If these side effects are observed, patients should be warned not to drive or use machine.

Taking with other medicines

It is especially important to tell your doctor if you are taking any of the following medicines:

- Medicines containing ibuprofen, aspirin other non-steroidal anti-inflammatory drugs (NSAID)
- Diuretics
- Medicines for high blood pressure (captopril, atenolol, losartan etc.)
- Anticoagulants (blood thinning medicines) (warfarin, heparin etc.)
- Lithium (used for mental disorders)
- Methotrexate (used for psoriasis, rheumatism and cancer diseases)
- Zidovudine (used for the treatment of HIV)
- Corticosteroids (used for the treatment of inflammation and immune system disorders)
- Probenecid (used to treat gout)
- Aminoglycosides (oral medicines used in diabetes)
- Oral hypoglycemic agents (blood sugar lowering drugs)

- Cardiac glycosides (used for heart failure)
- Ciclosporin or tacrolimus (used in organ transplants or in the treatment of certain immune system disorders)
- Quinolone antibiotics (ciprofloxacin, ofloxacin, levofloxacin etc.)
- Selective serotonin reuptake inhibitor (SSRI) antidepressant medicines
- Antiplatelet medicines (reducing the platelet count in the blood) (dipyridamole, clopidogrel)
- Nonsteroidal anti-inflammatory drugs (NSAIDs) can reduce the effectiveness of drugs used in the treatment of high blood pressure, such as ACE inhibitors, beta-blockers and diuretics. Diuretics can also increase the risk of nephrotoxicity (harmful effects on the kidneys) of nonsteroidal anti-inflammatory (NSAID) drugs
- Co-administration of cholestyramine (cholesterol-lowering drug) with ibuprofen may reduce the absorption of ibuprofen in the gastrointestinal tract. However, the clinical significance is unknown
- Co-administration of sulphonylurea with non-steroidal anti-inflammatory (NSAID) medications may potentiate the effect of sulphonylurea treatments. Blood sugar lowering has been reported very rarely with ibuprofen in patients who are on sulphonylurea treatment
- Mifepristone (a medicine used to terminate pregnancy) may theoretically cause a decrease in drug effectiveness due to the non-steroidal anti-inflammatory (NSAID) drugs' ability to reverse the prostaglandin effect. Limited evidence indicates that co-administration of prostaglandin with nonsteroidal anti-inflammatory (NSAID) drugs on the same day does not negatively affect the effects of mifepristone or prostaglandin on cervical ripening or uterine contractility (contraction of the uterus) and does not reduce the clinical efficacy of the medical termination of the pregnancy.
- Co-administration of CYP2C9 inhibitors (groups of drugs that stop the protein involved in the inactivation of drugs in the liver) with ibuprofen may increase exposure to ibuprofen (substance affecting the CYP2C9 enzymes). In a study with voriconazole and fluconazole (drugs used in the treatment of fungi, CYP2C9 inhibitors), approximately 80-100% increased exposure to S (+) - ibuprofen has been shown. Particularly in the case of high doses of ibuprofen combined with potent CYP2C9 inhibitors such as voriconazole or fluconazole, reduction of the dose of ibuprofen should be considered.
- Medicines that prevent blood clotting (e.g. warfarin); the anticoagulant effect may increase
- Ginkgo biloba herbal extract, the risk of bleeding in the gastro-intestinal tract may increase
- It should not be used with ticlopidine (a medicine that inhibits blood clotting)
- Other painkillers (other non-steroidal anti-inflammatory (NSAID) drugs including COX-2 inhibitors, e.g. aspirin, naproxen, celecoxib, nimesulide); combined use of two or more non-steroidal anti-inflammatory (NSAID) drug should be avoided.

There is also evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs (bleeding does not stop) receiving concurrent treatment with zidovudine (a drug used to treat infections caused by human immunodeficiency virus (HIV)) and ibuprofen.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How to use IBU-BABY?

- **Instructions for proper use and dosage/administration frequency:**

The maximum daily ibuprofen dose should be 3-4 doses and should not be more than 20-30 mg per kg of body weight. You should wait at least 6 hours between doses.

In children with body weight from 6.00 to 8.00 kg: One suppository is given at the beginning of treatment. If necessary, one more suppository can be given after 6-8 hours. Up to 3 suppositories can be given within 24 hours.

In children with body weight from 8.00 to 12.5 kg: One suppository is given at the beginning of treatment. If necessary, one more suppository can be given after 6 hours. Up to 4 suppositories can be given within 24 hours

IBU-BABY is used for a maximum of 3 days.

Consult your doctor if symptoms worsen or do not disappear during this time.

It is for short-term use only.

Undesirable effects can be minimized by using the lowest effective dose required to control disease symptoms as soon as possible.

- **Route and method of administration:**

The suppository is applied by inserting it into the rectum after the hands are thoroughly washed and dried.

To increase lubrication, warm the suppository with your hand before application or immerse it immediately in hot water for a very short time.

This medication is used for up to 3 days. During this period; if your child's pain and fever worsen, or if new symptoms appear, discontinue the treatment immediately and consult your doctor or pharmacist.

- **Different age groups:**

Use in children:

IBU-BABY should be used for children who are older than 6 months and whose body weight is at least 6.0 kg.

Use in elderly:

In the elderly, the incidence of undesirable effects such as gastrointestinal bleeding and perforation, which may be fatal on the digestive system, is increasing. Therefore, the smallest effective dose and the shortest duration of treatment should be preferred if it should be used in elderly patients.

- **Special populations:**

Kidney/Liver failure:

Caution should be exercised when used in patients with kidney, liver or heart failure because the use of ibuprofen may result in impaired renal function. In these patients, the dose should be kept as low as possible and renal function should be monitored.

It causes sedation (drowsiness) in patients with severe hepatic insufficiency.

Do not use IBU-BABY in case of liver failure.

If you have the impression that the effect of IBU-BABY is too strong or too weak, talk with your doctor or pharmacist.

If you use more IBU-BABY than you should:

If you used more IBU-BABY than you should or if a child accidentally swallowed the medicine, always consult a doctor or proceed to a nearest hospital for advice on the precautions to be taken and about the risk.

Symptoms may include nausea, abdominal pain, vomiting (may be bloody lines), headache, tinnitus, blurred consciousness, and nystagmus. Lethargy, chest pain, palpitations, loss of consciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, chills and respiratory problems have been reported with high doses.

In addition, somnolence, visual disturbances, rare decrease in blood pressure and renal failure may occur.

If you used more IBU-BABY than was prescribed, tell your doctor or pharmacist.

If you forget to use IBU-BABY:

Do not use a double dose to make up for a forgotten dose.

If you forget a dose, administer as soon as you remember. However, if it's time for the next dose, do not administer the missed dose.

Possible effects may occur when you stop taking IBU-BABY:

Not available.

4. Possible side effects

Like all medicines, IBU-BABY may cause side effects in patients sensitive to its ingredients.

If any of the following occur stop using IBU-BABY and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Shortness of breath; swelling of the face, lips, eye lids, tongue or throat; severe itching and rash in the skin; palpitations and dizziness due to low blood pressure (hypersensitivity - allergy)
- Wheezing and shortness of breath (asthma attack)
- Low blood pressure (hypotension)
- Irregular heartbeat, palpitation, chest pain
- Severe abdominal pain (gastric ulcer or pancreatitis)
- Yellowing of the eyes and the skin (liver dysfunction)
- Bloody or black tarry stools, vomiting blood or dark particles that look like coffee granules (gastrointestinal bleeding)

- Skin bruising, bleeding of the nose and gums, increased incidence of infectious diseases, pale skin and fatigue (bone marrow suppression)
- A severe disease occurring on the skin, mouth, eyes, and around genital organs and associated with peeling, swelling, blistering of the skin and fever (Stevens-Johnson syndrome)
- A disease with red skin rashes of different sizes or with water blisters in mouth and other areas of the body (erythema multiforme)
- A severe disease which water blisters and peeling skin and tissue loss (toxic epidermal necrolysis)
- Sudden loss of muscle strength, sensory loss, visual disturbances (stroke)
- Severe headache, stiffness of the neck, nausea, vomiting, fever and clouding of consciousness (aseptic meningitis)
- Seeing or hearing things that are not real (hallucinations)
- A severe skin reaction known as DRESS syndrome may occur. The symptoms of DRESS include rash, fever, swelling of lymph nodes and increased eosinophils (a kind of white blood cell).

These are very serious side effects.

If you have any of them, this means you have serious allergy to IBU-BABY. You may need urgent medical attention or to be hospitalized.

All of these very serious side effects occur very rarely.

Side effects are classified as shown in the following categories:

Very common: may be seen in at least 1 of 10 patients;

Common: may be seen less than 1 in 10 patients but more than 1 in 100 patients

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1,000 patients

Rare: may be seen less than 1 in 1,000 patients but more than 1 in 10,000 patients

Very rare: May affect up to 1 in 10000 patients

Not known: Cannot be estimated from the available data.

Common:

- Stomach disorders
- Abdominal pain
- Nausea

Uncommon:

- Asthma (respiratory disease with wheezing or shortness of breath)
- Bronchospasm (narrowing of respiratory tract ducts called bronchi in the lungs)
- Dyspnea (shortness of breath)
- Diarrhea
- Bloating
- Constipation
- Vomiting

- Stomach ulcer, perforation or hemorrhage
- Duodenum ulcer, perforation of hemorrhage
- Black stool
- Bloody vomiting
- Inflammation and ulceration of mouth mucosa
- Exacerbation of existing bowel diseases (ulcerative colitis, Crohn's disease)
- Rectum irritation
- Headache
- Dizziness
- Drowsiness
- Sleeplessness
- Tinnitus
- Tiredness, fatigue
- Allergic reactions such as hives (urticaria) and pruritus

Rare:

- Optic neuritis (inflammation of the optic nerve)

Very rare:

- Kidney failure (decrease in urine, water retention in the body (edema) and kidney tissue damage, increased serum urea density especially in long-term treatments)
- Hypertension
- Blood diseases (first symptoms: fever, sore throat, superficial wounds in the mouth, flu-like symptoms, severe fatigue, bleeding of the nose and skin bleeding)
- Skin reactions (erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome)
- Skin infections and soft-tissue infections that occur related to Chicken pox
- Aseptic meningitis (a type of inflammation of the meninges) symptoms such as stiffness of the neck, headache, nausea, vomiting, fever, and loss of sense of direction in some cases during treatment with ibuprofen of patients with immune system disorder (Systemic Lupus Erythematosus and mixed connective tissue disease)
- Serious hypersensitivity reactions may include: swelling of the face, tongue and throat, shortness of breath, accelerated heartbeat, decreased blood pressure (anaphylaxis, angioedema) or severe shock
- Exacerbation of asthma and bronchospasm (narrowing of respiratory tract ducts called bronchi in the lungs)
- Liver diseases (cholestatic jaundice, hepatitis, elevation of serum enzyme levels)
- Heart failure

IBU-BABY-like drugs have been associated with a small increase in the risk of heart attack and stroke, especially at high doses.

These are all serious side effects. Urgent medical attention may be required.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store IBU-BABY?

Store IBU-BABY in its original packaging and keep out of the reach and sight of children.

Store at room temperature below 25°C.

Use in compliance with the expiry date.

Do not use IBU-BABY after the expiry date which is stated on the package

Do not use IBU-BABY if you notice any damage to the product and/or package.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing authorization holder:

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