

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

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

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

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

- IBU-BABY is in the form of an almost white, uniformly looking suppository.
- IBU-BABY is presented in 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 given 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. What you need to know before you take IBU-BABY?

DO NOT use IBU-BABY

If;

- You are allergic to ibuprofen or non-steroidal anti-inflammatory/analgesic medicines or any of the ingredients in this medicine
- You have ever had 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 ever had gastrointestinal bleeding or perforation related to previous NSAIDs therapy
- You suffer from recurrent gastric-duodenal ulcers, inflammatory bowel diseases (ulcerative colitis, Crohn's disease), gastrointestinal bleeding or if you have had these diseases recurrently

- You have increased bleeding tendency (if there are cases of easy bleeding)
- You have severe liver impairment
- You have kidney impairment
- You have heart failure (NYHA Class IV)
- You are in the third trimester of pregnancy
- You are in the period before or after coronary artery by-pass surgery (operation for the correction of cardiac vessel obstruction)
- Your child's body weight is less than 6 kg and less than 6 months old

Use IBU-BABY with CAUTION

Cardiovascular (CV) Risk

- NSAIDs may cause increased risk of cardiovascular thrombotic events (related to clotting), myocardial infarction and stroke, which can be fatal. This risk may increase with duration of use. 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 characterized by symptoms related to inflammation of many tissues and organs such as unknown skin, joint, kidney, pericardium, pleura that shows different course and caused by malfunction of the immune system) and mixed connective tissue disease
- If there are 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 brain membrane inflammation (aseptic meningitis)
- If you have gastrointestinal discomfort, chronic inflammatory bowel disease (ulcerative colitis, Crohn's disease), rectal or anus diseases
- If you have high blood pressure and/or heart failure
- If you have ever had gastrointestinal bleeding or perforation related to previous ibuprofen therapy
- If you have liver impairment
- If you have allergic asthma, chronic rhinitis (long-standing rhinitis), sinusitis, nasal polyp (nasal flesh) or allergic discomfort or you have had these diseases before

- 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
- 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 (correction of cardiac vessel obstruction), peripheral vascular disease (weak circulation in legs or feet due to narrow 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 scarring in the gastrointestinal tract, which can be fatal
- If inflammation with blood blister, swelling and redness around the skin and eyes (Stevens-Johnson syndrome), a severe disease with water blister on the skin, skin peeling 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 occurs, 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 have vomiting blood or blood or darkening in your feces, stop using the medicine and consult a doctor. If ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs) are used for a long time, ulcers, bleeding and perforation may occur in the gastrointestinal tract even though this type of disease has not previously been experienced. The risk of the occurrence of such undesirable effects has already increased in those who have had 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 statements were applicable to you at any time in the past.

Using IBU-BABY with food and drink

It is not available 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 that may occur in terms of mother and 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 knowing that the use of ibuprofen may affect fertility negatively.

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

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

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

It is not known whether the medicine passes into breast milk. Because many medicines are secreted into breast milk and IBU-BABY has a potentially serious side-effect 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 machines

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 the machine.

Using 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 (for mental disorders)
- Methotrexate (for psoriasis, rheumatism and cancer diseases)
- Zidovudine (for HIV)
- Corticosteroids (for inflammation and immune system diseases)
- Probenecid (to treat gout)
- Aminoglycosides (medicines used orally in diabetes)
- Oral hypoglycemic agents (blood sugar lowering drugs)
- Cardiac glycosides (for heart problems)
- Cyclosporine or tacrolimus (used in organ transplants or in the treatment of certain immune system diseases)
- 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 (a kind of cholesterol reducing drug) with ibuprofen may reduce the absorption of ibuprofen in the gastrointestinal tract. However, the clinical significance is unknown
- Co-administration of sulphonylurea (a kind of sugar reducing drug) with non-steroidal anti-inflammatory (NSAID) medications may increase efficacy of sulphonylurea treatments. Very rare blood sugar reduction has been reported with ibuprofen in patients who are on sulphonylurea treatment
- Mifepristone (a drug 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 (medical termination)
- Co-administration of CYP2C9 inhibitors (groups of drugs that stop the protein involved in the inactivation of drugs in the liver) with the ibuprofen, ibuprofen (substance affecting the CYP2C9 enzymes) may increase exposure to ibuprofen. In a study with voriconazole and fluconazole (drugs used in the treatment of fungi, CYP2C9 inhibitors), approximately 80-100% increased ibuprofen exposure 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
- 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

At the same time, there is evidence of an increased risk of blood blister and accumulation of blood in joint space in patients with HIV (+) hemophilia (bleeding does not stop) receiving zidovudine (a drug used in the treatment of infections caused by human immunodeficiency virus (HIV)) and ibuprofen therapy.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

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 be no more than 20-30 mg per kg of body weight. No application should be done more frequently than 6 hours.

In children with body weights from 6.00 to 8.00 kg: One suppository is used 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 weights from 8.00 to 12.5 kg: One suppository is used 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.

Patients should be informed that they should consult a doctor if symptoms do not disappear or become severe during this time.

It is for short time use.

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 back passage after the hands are thoroughly washed and dried.

To increase the lubricity, warm it with your hand before applying the suppository or immerse it in hot water for a very short period of time.

This medication is used for up to 3 days. During this period; if your child's pain and fever are getting worse, or if new symptoms appear, stop 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 old 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. For this reason, the smallest effective dose and the shortest duration of treatment should be preferred if elderly patients need to be used.

- **Special populations:**

Kidney/Liver/Heart failure:

Caution should be used 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 hepatic insufficiency.

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

If you used more IBU-BABY than you should:

If you have used more IBU-BABY than you should, or if the children have used this medicine by accident, always consult a doctor or nearest hospital for advice on the measures to be taken and opinion on the risks.

Symptoms may include nausea, abdominal pain, vomiting (bloody lines can be seen), headache, ringing in the ears, clouding of consciousness, and uncontrolled eye movements. At high doses, drowsiness, chest pain, palpitation, loss of consciousness, contractions (especially in children), weakness and dizziness, blood in the urine, chills, respiratory problems have been reported.

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

If you may have taken more IBU-BABY than you should, talk to a 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, take it as soon as you remember. However, if it is time for the next dose, do not take the missed dose.

If you stop using IBU-BABY:

Not available.

4. Possible side effects

Like all medicines, side effects can occur in people sensitive to the contents of IBU-BABY.

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 your face, lips, tongue, eye lids or throat; severe itching and rash in the skin; palpitations and dizziness due to low blood pressure (hypersensitivity - allergy)
- Wheezing and difficult breathing (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 coffee grain vomitus and stool (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 collection of water in mouth and other areas of the body (erythema multiforme)
- A severe disease which is encountered by water filled swellings on the skin, skin peeling, and tissue loss (toxic epidermal necrolysis)
- Sudden loss of muscle strength, loss of sensation, visual disturbances (stroke)
- Severe headache, stiffness of the neck, nausea, vomiting, fever and decreased level of consciousness (aseptic meningitis)
- Seeing or hearing things that are not real (hallucinations)
- A severe skin reaction known as DRESS syndrome may develop. Signs of DRESS are rash, fever, swelling of lymph nodes and increased eosinophils (a type 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 emergency medical care or hospitalization.

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 at least 1 in 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 be seen less than 1 in 10.000 patients

Unknown: it cannot be estimated from the available data.

If any of the following occur, immediately inform your doctor or go to the nearest emergency department:

Common:

- Stomach disorders
- Abdominal pain
- Nausea

Uncommon:

- Asthma (respiratory disease with wheezing or difficult breathing)
- 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 ulcer in the 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:

- Renal insufficiency (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 brain membrane inflammation) symptoms such as stiffness of the neck, headache, nausea, vomiting, fever, and loss of sense of direction in some cases in treatment with ibuprofen in patients with immune system disease (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.

If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.

5. How to store IBU-BABY?

Keep IBU-BABY in the original package and out of the reach and sight of children.

Store at room temperature below 25°C.

Use in accordance 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.

Marketing authorization holder:

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

This patient information leaflet was last approved on 18/09/2018.