PATIENT INFORMATION LEAFLET

IBU-FORT 200 mg/5 ml suspension
For oral use only.

- ***Active substance:*** Each 5 ml (1 measure) suspension contains 200 mg ibuprofen.
- ***Excipients:*** Xanthan gum, hydroxypropyl methyl cellulose, glycerin, sorbitol (70%) (E420), maltitol (E965), sodium benzoate (E211), sucrose, polyoxyl 40 castor oil (PEG 40), citric acid, strawberry flavor, ammonium glycyrrhizate, microcrystalline cellulose and carmellose sodium, masking flavor, deionized water.

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-FORT is and what it is used for?

- IBU-FORT is a suspension containing 200 mg ibuprofen in each measuring pipette (5 ml) and presented in amber colored glass 30 ml or 100 ml solution containing bottles (Type III) closed with pilfer-proof high density polyethylene (HDPE) cap and low density polyethylene seal with 1 plastic pipette of 5 ml graduated with 0.5 ml.

- It is used in the treatment of rheumatic pains, musculoskeletal pain, menstrual cramp and fever.

2. Before you use IBU-FORT

Cardiovascular (CV) Risk
Risks related to Cardiovascular System
- Non-steroidal anti-inflammatory drugs (NSAIDs) may cause a potentially fatal coagulation (KV thrombotic) event, a heart attack (myocardial infarction) and an increased risk of stroke. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

-IBU-FORT should not be used (contraindicated) for treatment of pain before surgery performed to improve obstruction in coronary veins (coronary artery by-pass surgery).

Risks Related to Digestive System
Non-steroidal anti-inflammatory drugs (NSAIDs) cause serious adverse events associated with the gastrointestinal system 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.

Do not use IBU-FORT:

- If you are in the last trimester of pregnancy
- If you have hypersensitivity (allergic) to ibuprofen or any of the excipients in the product
- If you have previously showed allergic reactions such as asthma, nasal inflammation (rhinitis), or hives (urticaria) against ibuprofen, aspirin, and other NSAIDs
- If you have had a previous gastrointestinal bleeding or perforation because of the mentioned drugs
- If you have had diseases such as recurrent gastrointestinal ulcers, inflammatory bowel diseases (ulcerative colitis, Crohn's disease), gastrointestinal bleeding or you have had them before repetitively
- If you have severe cardiac failure
- If you have severe liver failure
- If you have severe kidney failure
- during the period before or after coronary artery by-pass surgery (operation for the correction of cardiac vessel obstruction)
- If gastrointestinal bleeding or wounds (ulcerations) occur during ibuprofen use,
- If you have cerebrovascular bleeding or other active bleeding
- If you have increased bleeding tendency
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Take special care with IBU-FORT:
- It may cause bronchial spasm if you are an asthma patient or you had a previous asthma attack
- If you previously had gastrointestinal ulcers or other gastrointestinal diseases, they may flare up
- If ou have kidney disease, the kidney functions should be followed up. The risk of kidney function worsening is increased in people, who take ibuprofen and similar NSAIDs for a long time; who have heart failure and liver disorders; who take drugs increasing urine output (diuretics) and antihypertensive drugs belonging to ADE inhibitor class; and who are elderly
- If you have liver disease

- If you have heart disease or hypertension (high blood pressure); fluid retention and as a result of it swellings (edema) may be observed in various parts of the body

- When ibuprofen and similar drugs are used for especially at high doses and for long-time periods, they were detected to be related to a small increase in risk of heart attack (myocardial infarction) or stroke. Treatment should be consulted with the physician or the pharmacist in people who have heart or vascular diseases; have previous stroke or have risks for such conditions (high blood pressure, high cholesterol or diabetes disease or smokers)
- If ibuprofen and similar NSAIDs are used for a long time period (continuous use), although you have not had such a disease before, ulcers, bleeding and perforations may occur in the gastrointestinal tract. The risk of such undesired effects is increased in subjects who have had such a disease before, in elderly people, at high drug doses, and during long-term treatments.
- If you realize purple coloring or bruises without unknown origin in your body, consult your physician
- Immediately consult your physician if there are chill, tremor and sudden increase in fever, fatigue, headache and vomiting or neck stiffness; these may be symptoms of a type of brain membrane inflammation (aseptic meningitis)
- If you have redness and rash on your skin

Similar to the other NSAIDs, IBU-FORT can also mask signs of infection. The administration of the lowest dose which will relieve the signs of your disease for the shortest treatment duration will minimize the undesired effects of the drug.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using IBU-FORT with food and drink:
It can be taken on an empty stomach. However, mild indigestion may occur in very few people. If such a condition develops, it will help to take the required doses with some food or milk. Do not take IBU-FORT with alcohol. If you are drinking more than three glasses a day, ibuprofen may increase the risk of stomach bleeding. Do not use with orange juice and cola. IBU-FORT should be taken at least one hour before or two hours after these foods.

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

Use of IBU-FORT should be avoided during pregnancy whenever possible.

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 recommended for administration in breastfeeding women.

Effects on ability to drive and use of machines
Time to react to certain stimuli can be affected in some patients receiving ibuprofen. This should be taken into account in case of drive and use of machines that require high attention. Use of high doses may cause side effects such as fatigue and headache in central nervous system. This effect may be increased with concomitant alcohol intake.

Important information about some of the excipients of IBU-FORT
Each one dose (5 ml) contains 1,875 g sucrose. This should be considered in patients with diabetes.

As it contains sorbitol (E420), maltitol (E965) and sucrose, if you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking IBU-FORT.

IBU-FORT contains less than 1 mmol (23 mg) of sodium per dose (5 ml); i.e. it is "sodium free".

Polyoxyl 40 castor oil (PEG 40) contained in the content of IBU-FORT may cause nausea and diarrhea.

Using with other medicines
Because interactions were reported in some patients, when you are having IBU-FORT treatment you should be careful if you are receiving any of the drugs listed below:

- Aminoglycoside class antibiotics (i.e. gentamicin, kanamycin, streptomycin)
- Drugs for high blood pressure
- Drugs preventing blood coagulation (i.e. warfarin)
- Drugs inhibiting thrombocytes, which provide coagulation (antithrombocyte agents, i.e. aspirin dipyridamole, clopidogrel) and selective serotonin re-uptake inhibitors used for depression (i.e., fluoxetine, fluvoxamine, paroxetine, sertraline)
- Aspirin
- Ginkgo biloba herbal extract
- Drugs increasing urine output (i.e. furosemide)
- Cardiac glycosides used for heart failure (i.e. digoxin, digitoxin)
- Cholestyramine used in the treatment of high cholesterol
- Sulphonylurea drugs used to lower the blood sugar level
- Other analgesics (other NSAIDs including COX-2 inhibitors i.e. aspirin, naproxen, celecoxib, nimesulide)
- Cortisone group drugs
- Lithium salts (used in psychiatric disease treatments) and methotrexat (a drug used in rheumatic joint diseases, and in some cancer types)
- Mifepristone (miscarriage drug)
- An antibiotic, cyclosporine
- Tacrolimus, a drug used to prevent your body from rejecting the transplanted organ after organ transplant operations
- Zidovudine used in the treatment of AIDS (HIV infection)
- A group of drugs called CYP2C9 inhibitors that inhibit liver proteins that neutralize drugs

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-FORT?

- **Instructions for appropriate method and dose/frequency of administration:**

Absorption is accelerated when IBU-FORT is taken on an empty stomach, but it is recommended to be taken preferably after meals to minimize gastrointestinal side effects.

Adults:
The average dose for mild to moderate pain is 1.200 mg.

The daily dose is 200 mg to 400 mg per 4-6 hours depending on the condition of the patient.

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:**

For oral administration.

Shake well the bottle before use.

- **Different age groups:**

Use in children:
It is not recommended for use in children under 6 years.

Pediatric use (6-12 ages):

- For pain and fever 5-10 mg/kg/dose as 3-4 doses

Age	Weight (Average weight)	Ibuprofen Dose (minimum-maximum)	Measure (minimum-maximum)
6	18-22 kg (20 kg)	100 mg - 200 mg	2,5 ml - 5 ml
7-10	22-26 kg (24 kg)	120 mg - 240 mg	3 ml - 6 ml
11-12	30-34 kg (32 kg)	160 mg - 320 mg	4 ml - 8 ml

- For juvenile arthritis 30-40 mg/kg/day as 3-4 divided doses

Use in elderly:
The frequency of adverse effects that may occur in the elderly digestive system is increased. Thus, if it needs to use for elderly patients, the possible smallest effective dose and the shortest duration of treatment should be preferred.

- **Special populations:**

Kidney/Liver/Cardiac failure:
Should not use it, if you have severe kidney, liver or heart failure.

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

If you have used more IBU-FORT than you should:
If you may have taken more IBU-FORT than you should, talk to a doctor or pharmacist.

If you have used more IBU-FORT than you should use, or if children have used this medicine accidentally, always consult a doctor or the nearest hospital for advice on the measure to be taken and for opinion on the risk.

Symptoms may include nausea, abdominal pain, vomiting (may be bloody lines), headache, tinnitus, blurring of consciousness, and shaky eye movements (nystagmus). At high doses, drowsiness, chest pain, palpitations, loss of consciousness, contractions (especially in children), weakness and dizziness, blood in the urine, chills and respiratory problems have been reported.

If you forget to use IBU-FORT:

If you have forgotten to take your medicine, take it as soon as you remember. However, if it is time for the next dose, do not take the missed dose.

Do not use double dose to make up for the dose you forgot.

If you stop using IBU-FORT:

It is very important to keep taking IBU-FORT until your doctor tells you to stop. Do not stop treatment even if you feel better. If you do stop, the symptoms may worsen.

The administration of the lowest dose which will relieve the signs of your disease for the shortest treatment duration will minimize the undesired effects of the drug.

If you have any further questions about the use of this drug, please ask your doctor or pharmacist.

4. Possible side effects

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

Side effects were listed 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 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

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 stop using IBU-FORT 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 on the skin; palpitations and dizziness resulting from low blood pressure (Hypersensitivity – Allergy)
- Wheezing or difficult breathing (asthma attack)
- Increased blood pressure (hypertension)
- Irregular heart rate, palpitations, chest pain
- Severe abdominal pain (stomach ulcers or pancreatitis)
- Yellowing of the eyes and skin (liver dysfunction)

- Any blood or black color that look like coffee grounds in stool or vomit (gastrointestinal bleeding)
- Skin bruising, bleeding of the nose and gums, increased incidence of infectious diseases, pale skin and fatigue (bone narrow suppression)
- 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 serious disease associated with skin blisters filled with liquid and peeling and loss of the skin (toxic epidermal necrolysis)
- Sudden loss of muscle strength, loss of sensation, visual disorders (stroke)
- Severe headache, stiffness of the neck, nausea, vomiting 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 occur. The symptoms of DRESS are as follows; rash, fever, swelling of lymph nodes and increase in 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-FORT. You may need emergency medical care or hospitalization.
These very serious side effects occur very rarely.

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

Common:
- Sleepiness, fatigue
- Headache and dizziness
- Blurred vision
- Digestive problems (dyspepsia)
- Diarrhea
- Nausea, vomiting, abdominal pain
- Excessive floating in stomach and intestines (flatulence)
- Decreased or diminished colon motility (constipation)
- Gastrointestinal bleeding
- Tar colored, foul smelling defecation (melaena)
- Bloody or coffee grain vomitus (hematemesis)
- Rash

Uncommon:
- Visual defects
- Wound in duodenum (duodenal ulcer)
- Wound in the stomach (gastric ulcer)
- Inflammation of the inner membrane of the stomach (gastritis)
- Mouth inflammation prominent by small wounds (oral ulceration)
- Jaundice
- Liver inflammation (hepatitis)
- Liver function disorder
- Flurry, restlessness

- Numbness (paresthesia)
- Hearing disorder (decreased or increased hearing)
- Common cold (rhinitis), influenza
- Asthma, deterioration of asthma, bronchospasm or difficulty in breathing (dyspnea) like respiratory tract reactions,
- Hives (urticaria)
- Itching (pruritus)
- Small hemorrhages on the skin and mucosa (purpura)
- Hypersensitivity (angioedema) causing swelling in the face and throat (edema)
- Sensitivity to light (photosensitivity)
- Painful urination
- Difficult urination in male patients (urinary retention)
- Kidney failure (such as swelling in the ankles)
- Decreased number of white blood cells (leukocyte) (leukopenia)
- Decreased number of cells mediating thrombocyte-blood coagulation (thrombocytopenia)
- Sudden onset, decreased number of white blood cells (agranulocytosis)
- Severe depletion of blood cells (aplastic anemia)
- Hemolytic anemia (a type of anemia)
- Sleepiness (somnolence)
- Sleeplessness and anxiety (concern, worry)

Rare:

- Excessive decrease in the number of neutrophils with a characteristic white blood cell variety (neutropenia)
- Ringing in the ears (tinnitus)
- Seeing, feeling or hearing fictitious things (hallucination)
- Dizziness due to a disorder in the inner ear (vertigo)
- With symptoms such as stiffness of the neck, headache, nausea, vomiting, fever or loss of orientation) (aseptic meningitis) particularly in patients with autoimmune diseases such as systemic lupus erythematous and mixed connective tissue disease
- Widespread, severe allergic reaction (anaphylaxis)
- Delirium
- Increased heart rate (tachycardia)
- High blood pressure (hypertension)
- Heart rhythm disorder
- Inflammation in the eye nerve (Optic neuritis)
- Inflammation in the eye due to a toxic substance (toxic optic neuropathy)
- Dry mouth
- Perforation in the stomach or intestines (gastrointestinal perforation)
- Damage in the liver
- Edema
- Allergic skin rash (allergic dermatitis)

Very rare:

- Pancreas inflammation (pancreatitis)
- Liver failure
- In the skin, in the mouth, in the eyes, around genitals; severe bullous skin inflammation, including Stevens-Johnson syndrome with skin peeling, swelling, bubbles and fever

- 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 pealing, and tissue loss (toxic epidermal necrolysis)
- Blockage of heart arteries by a blood clot

Unknown:
- Allergic reaction and hypersensitivity reaction causing swelling in the face and throat (angioedema)
- Lack of appetite
- Inflammation of colon (colitis) and Crohn's disease (a kind of inflammatory bowel disease) episode
- Blood disorders (dyscrasia)
- Thickening of sputum

Drugs like IBU-FORT, especially when used over dose (2400 mg/day) may cause a small increase in the risk of heart attack (myocardial infarction) or stroke.

Rarely IBU-FORT may cause blood disorders and kidney problems.

These are very serious side effects. Emergent medical care may be required.

All of these serious side effects occur rarely.

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

5. How to store IBU-FORT?
Keep in the original package and out of the reach and sight of children.
Store below 25 °C at room temperature.

Use in accordance with the expiry date.
Do not use IBU-FORT after the expiry date indicated on the package.

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

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