Package leaflet: Information for the user

Ibu AIWA 400 mg film-coated tablets
For use in children aged 6 years and over, adolescents and adults
Ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4 "Possible Side Effects".

Contact your doctor if the symptoms get worse or do not
- after 3 days for children and adolescents
- after 3 days for fever or 4 days for pain in adults.

What is in this leaflet

1. What Ibu AIWA 400 mg is and what it is used for

Ibu AIWA 400 mg is a medicine that relieves pain, fever and inflammation (non-steroidal anti-inflammatory drug/antirheumatic agent, NSAID).

Ibu AIWA 400 mg is used for the short-term symptomatic treatment of
- mild to moderate pain, such as headache, toothache, period pains;
- fever.

If you do not feel better or even worse after 3 or 4 days, contact your doctor.

2. What you need to know before you take Ibu AIWA 400 mg

Do not take Ibu AIWA 400 mg
- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6);
- if you have a history of bronchospasm, asthma attacks, swelling of the nasal lining or skin reactions or sudden swelling after taking acetylsalicylic acid or other non-steroidal anti-inflammatory agents;
- if you have unexplained problems of blood formation;
- if you have, or have a history of, recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (at least 2 different episodes of confirmed ulcers or bleeding);
- if you have a history of gastrointestinal bleeding or perforation associated with previous treatment with non-steroidal anti-inflammatory drugs/antirheumatic agents (NSAIDs);
- if you have bleeding in the brain (cerebrovascular bleeding) or other active bleeding;

- if you have severe liver or kidney dysfunction;
- if you have a severely weak heart (heart failure);
- severe dehydration (e.g. caused by vomiting, diarrhoea or insufficient fluid intake);
- in the last three months of pregnancy;
- in children under 20 kg (6 years), as this dose strength is generally not suitable due to the active substance content.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ibu AIWA 400 mg.

If you have an infection - see below under "Infections".

Side effects can be minimised by using the lowest effective dose over the shortest period of time needed to bring symptoms under control.

Gastrointestinal tract safety
Combined use of Ibu AIWA 400 mg with other non-steroidal anti-inflammatory drugs, including so-called COX-2 inhibitors (cyclooxygenase-2 inhibitors), should be avoided.

Elderly patients
In elderly patients, side effects occur more frequently after use of NSAIDs, especially gastrointestinal bleeding and perforation, which may be life-threatening in some cases. For this reason, particularly close medical surveillance is required in elderly patients.

Bleeding of the gastrointestinal tract, ulcers and perforation
Bleeding of the gastrointestinal tract, ulcers and perforation, including with fatal outcome, have been reported during treatment with all NSAIDs. This has occurred at any time during therapy, with or without previous warning symptoms or a history of serious gastrointestinal events.

The risk of experiencing gastrointestinal bleeding, ulcers and perforation is higher with increasing NSAID dose, in patients with a history of ulcers, especially with complications of bleeding or perforation (see section 2: "Do not take Ibu AIWA 400 mg"), and in elderly patients. These patients should start treatment at the lowest available dose.

For these patients, as well as for patients requiring additional treatment with low-dose acetylsalicylic acid (ASA, aspirin) or other medicines that may increase the risk of gastrointestinal disorders, combination treatment with medicines to protect the stomach lining (e.g. misoprostol or proton pump inhibitors) should be considered.

If you have a history of side effects affecting the gastrointestinal tract, especially if you are elderly, you should report all unusual abdominal symptoms to your doctor (especially gastrointestinal bleeding), particularly at the start of therapy.

Caution is advised if you are also taking other medicines that may increase the risk of ulcers or bleeding, e.g. oral corticosteroids, anticoagulants (blood-thinners) such as warfarin, selective serotonin reuptake inhibitors (used to treat disorders including depression) or platelet aggregation inhibitors such as ASA (see section 2: "Other medicines and Ibu AIWA 400 mg").

Treatment must be stopped if you develop gastrointestinal bleeding or ulcers during treatment with Ibu AIWA 400 mg.

NSAIDs should be used with caution in patients with a history of gastrointestinal disorders (ulcerative colitis, Crohn's disease), as their condition may get worse (see section 4).

Effects on the cardiovascular system
Anti-inflammatories/painkillers such as ibuprofen may be associated with a slightly increased risk of heart attack or stroke, especially when used at high doses. Do not exceed the recommended dose or duration of treatment without consulting your doctor.

Before taking Ibu AIWA 400 mg, you should discuss your treatment with your doctor or pharmacist if you

- have a heart condition, including a weak heart (heart failure) and angina (chest pain), or have had a heart attack, bypass surgery, peripheral arterial occlusive disease (poor blood circulation in the legs or feet due to narrowed or blocked arteries) or any type of stroke (including a mini-stroke or a transient ischaemic attack, "TIA").
- have high blood pressure, diabetes or high cholesterol levels or have a family history of heart disease or strokes or if you smoke.

Skin reactions
Serious skin reactions have been reported in association with the treatment with Ibuprofen. You should stop treatment with Ibu AIWA 400 mg and seek medical attention immediately at signs of skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

During a chickenpox infection (varicella infection), use of Ibu AIWA 400 mg should be avoided.

Infections

Ibu AIWA 400 mg may hide signs of infections such as fever and pain. It is therefore possible that Ibu AIWA 400 mg may delay appropriate treatment of infection which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chicken pox. If you take this medicine while you have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

Other warnings
Ibu AIWA 400 mg should be used only after careful consideration of the benefit/risk balance:

- if you have certain congenital problems of blood formation (e.g. acute intermittent porphyria).
- if you have certain autoimmune diseases (systemic lupus erythematosus and mixed connective tissue disease).

Particularly close medical surveillance is required:

- if you have gastrointestinal disorders or a history of chronic inflammatory bowel diseases (ulcerative colitis, Crohn's disease),
- if your kidney function is impaired
- in case of liver dysfunction
- in case of high blood pressure or weak heart (hear failure),
- if you have allergies (e.g. skin reactions to other medicines, asthma, hay fever), chronic nasal swelling of the nasal lining or chronic obstructive pulmonary disease

Severe acute hypersensitivity reactions (e.g. anaphylactic shock) are very rarely observed. At the first signs of a severe hypersensitivity reaction after taking/administration Ibu AIWA 400 mg, treatment must be stopped. Any medical procedures required must be implemented by healthcare professionals, depending on the symptoms.

Ibuprofen can temporarily inhibit blood platelet function (platelet aggregation). Patients with blood clotting disorders should therefore be carefully monitored.

During prolonged application of Ibu AIWA 400 mg, regular monitoring of liver function tests, kidney function and blood counts is required.

If Ibu AIWA 400 mg is taken before surgical procedures, the doctor or dentist must be consulted/informed.

Prolonged use of any type of painkiller for headache can make it worse. In such cases or if this is suspected, medical advice should be sought and treatment stopped. The diagnosis of medication use headache (medication overuse headache, MOH) should be suspected in patients suffering from frequent or daily headaches, even though (or precisely because) they regularly take medicines for headache.

In general, habitual intake of painkillers, especially when several pain-killing agents are combined, may lead to permanent kidney damage, with a risk of kidney failure (analgesic nephropathy).

Children and adolescents
There is a risk of kidney dysfunction in dehydrated children and adolescents.
Please note the instructions in section 2: “Do not take Ibu AIWA 400 mg”.

Other medicines and Ibu AIWA 400 mg
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of Ibu AIWA 400 mg may affect the effect of other medicines; conversely, the effect of Ibu AIWA 400 mg may be affected by the effect of other medicines. For example:
- Medicines with an anticoagulant effect (i.e. that thin the blood/prevent blood clotting, e.g. acetylsalicylic acid , warfarin, ticlopidine).
- Medicines that lower high blood pressure (ACE inhibitors such as captopril, beta-blockers such as medicines containing atenolol, angiotensin-II receptor antagonists such as losartan)

A few other medicines can also affect – or may themselves be affected by – treatment with Ibu AIWA 400 mg. Therefore, you should always seek the advice of your doctor or pharmacist before using Ibu AIWA 400 mg together with other medicines.

Combined use of Ibu AIWA 400 mg and digoxin (used to strengthen the heart), phenytoin (used to treat seizures) or lithium (used to treat mental illnesses) can increase the concentration of these medicines in the blood. Monitoring of serum lithium levels, serum digoxin levels and serum phenytoin levels is generally not required when used as directed (for 4 days maximum).

Ibu AIWA 400 mg can reduce the effect of medicines used to increase urine output and lower blood pressure (diuretics and antihypertensive agents).

Ibu AIWA 400 mg can reduce the effect of ACE inhibitors (used to treat heart failure and high blood pressure). Furthermore, during combined use, the risk of experiencing kidney dysfunction may be increased.

Combined administration of Ibu AIWA 400 mg and potassium-sparing diuretics (certain types of water tablet) can lead to an increase in blood potassium levels.

Combined use of Ibu AIWA 400 mg with other anti-inflammatories and painkillers of the non-steroidal anti-inflammatory group or with glucocorticoids increases the risk of gastrointestinal ulcers or bleeding.

Combined use of platelet aggregation inhibitors and certain antidepressants (selective serotonin reuptake inhibitors/SSRIs) can increase the risk of gastrointestinal bleeding.

Administration of Ibu AIWA 400 mg within 24 hours before or after administration of methotrexate can lead to increased concentrations of methotrexate and an increase in its undesirable effects.

The risk of a nephrotoxic (kidney-damaging) effect by ciclosporin (medicine used to prevent transplant rejections and to treat rheumatic disorders) is increased when administered at the same time as certain non-steroidal anti-inflammatory drugs. This effect cannot be ruled out for the combination of ciclosporin with ibuprofen.

Medicines containing probenecid or sulfinpyrazone (used to treat gout) may delay the excretion of ibuprofen. This can cause Ibu AIWA 400 mg to accumulate in the body, with an increase in its undesirable effects.

NSAIDs may possibly increase the effect of blood-thinners such as warfarin. Monitoring of the clotting status is recommended during combined treatment.

Clinical studies have shown interactions between NSAIDs and sulfonylureas (used to lower blood sugar). By combined use of Ibu AIWA 400 mg and sulphonylureas , it is recommended to check the blood glucose levels as a precaution.

Tacrolimus: The risk of kidney damage is increased when both medicines are administered at the same time.

Zidovudine: There is evidence to suggest a higher risk of bleeding into joints (haemarthrosis) and haematoma in HIV-positive haemophilic patients taking zidovudine and ibuprofen at the same time.

Antibiotics from the quinolone group: The risk of seizures may be increased if both medicines are taken at the same time.

The concomitant use of ibuprofen and CYP2C9 inhibitors may increase exposure to ibuprofen (a CYP2C9 substrate). In a study with voriconazole and fluconazole (CYP2C9 inhibitors), exposure to S(+) ibuprofen was shown to increase by approximately 80 to 100 per cent. A reduction in the dose of ibuprofen should be considered if potent CYP2C9 inhibitors are used concomitantly, especially if high doses of ibuprofen are co-administered with either voriconazole or fluconazole.

Ginkgo biloba (a herbal medicine) may increase the risk of bleeding from NSAIDs.

Ibu AIWA 400 mg with alcohol

Because side effects, especially central nervous side effects and side effects in the gastrointestinal tract, may be increased, you should avoid drinking alcohol if possible while using Ibu AIWA 400 mg.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
If pregnancy is confirmed while you are using Ibu AIWA 400 mg, you must tell your doctor. You may only use ibuprofen in the first six months of pregnancy after consultation with your doctor. In the last three months of pregnancy, Ibu AIWA 400 mg must not be used due to the increased risk of complications for the mother and child.

Breast-feeding
The active substance ibuprofen and its metabolites pass into breast milk just in small amounts. As no adverse effects for the infant have so far been reported, discontinuation of breast-feeding is generally not required in short-term use of the recommended dose.

Fertility
Ibu AIWA 400 mg belongs to a group of medicines (non-steroidal antirheumatic agents) that can affect the fertility of women. This effect is reversible after stopping this medicine.

Driving and using machines
As central nervous side effects, such as tiredness and dizziness, may occur when using Ibu AIWA 400 mg at higher doses, the ability to react may be altered in individual cases and the ability to drive and use machines may be impaired. This particularly applies in interaction with alcohol. As a result, you may no longer be able to react quickly enough and appropriately enough to unexpected and sudden events. In this case, do not drive your car or other vehicles. Do not use any tools or machines. Do not work without a firm foothold.

3. How to take Ibu AIWA 400 mg

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In adults, if the use of this medicine is necessary for more than 3 days for fever or for more than 4 days for pain, or if the symptoms worsen, medical advice should be sought.
If children and adolescents need to take this medicine for more than 3 days or if symptoms worsen, medical advice should be sought.

The recommended dose is:

Body weight **Age**	**Single dose**	**Maximum daily dose**
20 to 29 kg (children: 6 - 9 years old)	½ film-coated tablet (equivalent to 200 mg ibuprofen)	up to 1 ½ film-coated tablets (equivalent to a maximum of 600 mg ibuprofen)
30 to 39 kg (children:10 - 11 years old)	½ film-coated tablet (equivalent to 200 mg ibuprofen)	2 film-coated tablets (equivalent to 800 mg ibuprofen)
≥ 40 kg (adolescents from 12 years and adults	½ to 1 film-coated tablet (equivalent to 200-400 mg ibuprofen)	3 film-coated tablets (equivalent to 1200 mg ibuprofen)

If you have taken the maximum single dose, wait for at least 6 hours before taking the next dose.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see Section 2)

Dosage in the elderly:
There is no special dose adjustment required.

The tablet can be divided into equal doses.

Method of administration
Please take the film-coated tablet whole with plenty of liquid (e.g. a glass of water).
This promotes the onset of action. The film-coated tablets can be taken independently of meals. For patients who have a sensitive stomach, it is recommended to take Ibu AIWA 400 mg during meals.

Please talk to your doctor or pharmacist if you have the impression that the effect of Ibu AIWA 400 mg is too strong or too weak.

If you take more Ibu AIWA 400 mg than you should

If you have taken more Ibu AIWA 400 mg than you should, or if children have accidentally taken the medicine, always contact a doctor or hospital near you for an assessment of the risk and advice on further treatment.

The symptoms of an overdose may include nausea, stomach pain, vomiting (possibly including blood), headache, ringing in the ears, confusion and eye tremor. Bleeding in the gastrointestinal tract are possible. At high doses, drowsiness, dizziness, chest pain, palpitation, fainting, convulsions (especially in children), weakness and dizziness, blood in the urine, liver and kidney dysfunction, decreased breathing (respiratory depression), drop in blood pressure, blue-red colouration of skin and mucous membranes (cyanosis), freezing and breathing problems have been reported.

Metabolic acidosis may occur in cases of severe poisoning.

There is no specific antidote.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following categories are used for expressing the frequency of side effects:

very common:	may affect more than 1 in 10 patients treated
common:	may affect up to 1 to 10 patients treated
uncommon:	may affect up to 1 to 100 patients treated
rare:	may affect up to 1 to 1,000 patients treated
very rare:	may affect up to 1 to 10,000 patients treated
not known:	frequency cannot be estimated from the available data

Possible side effects
The list of the following undesirable effects includes all side effects reported during treatment with ibuprofen, including those during high-dose long-term therapy in patients with rheumatism. Frequencies beyond very rare reports relate to the short-term use of daily doses up to a maximum of 1200 mg ibuprofen (= 3 Ibu AIWA 400 mg).

Regarding the following adverse drug reactions, it must be remembered that these are mainly dose-dependent and vary from patient to patient.

The most commonly observed side effects involve the digestive tract.
Stomach/duodenal ulcers (peptic ulcers), perforation or bleeding, sometimes fatal, may occur, especially in elderly patients (see section 2 "warnings and precautions"). Nausea, vomiting, diarrhoea, flatulence, constipation, digestive problems, abdominal pain, tarry stools, vomiting blood, inflammation of the oral mucosa with ulceration (ulcerative stomatitis),worsening of colitis and Crohn's disease (see section 2 "warnings and precautions") have been reported after use. Less commonly, inflammation of the stomach lining has been observed. In particular, the risk of experiencing gastrointestinal bleeding depends on the dose range and duration of use.

Oedema, high blood pressure and heart failure have been reported in association with NSAID treatment.

The administration of medicines like Ibu AIWA 400 mg are possibly associated with a slightly increased risk of heart attack (myocardial infarction) or stroke.

Infections and infestations
Very rare: worsening of infection-related inflammation (e.g. development of necrotising fasciitis) has been described in temporal association with the use of certain anti-inflammatory agents (non-steroidal anti-inflammatory drugs; to which Ibu AIWA 400 mg also belongs).

Very rare: symptoms of aseptic meningitis (inflammation of the brain lining not caused by infection) have been observed during use of ibuprofen, such as severe headache, nausea, vomiting, fever, stiff neck or impaired consciousness. There seems to be an increased risk for patients already suffering from certain autoimmune diseases (systemic lupus erythematosus, mixed connective tissue disease).

If signs of infection appear for the first time or get worse during the use of Ibu AIWA 400 mg (e.g. redness, swelling, overheating, pain, fever), a doctor should be consulted immediately.

Blood and lymphatic system disorders
Very rare: disorders of blood formation (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis).
First signs may be: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nosebleeds and bruising.
In these cases, you must stop using this medicine immediately and consult a doctor. You should not attempt to treat such disorders yourself with medicines to reduce pain and fever.

Immune system disorders
Uncommon: hypersensitivity reactions with skin rash and itchy skin, as well as asthma attacks (if necessary drop in blood pressure).
In this case, you must tell a doctor immediately and stop taking Ibu AIWA 400 mg.

Very rare: severe general hypersensitivity reactions. These may manifest as: facial oedema, swollen tongue, swelling of the inner larynx with airway constriction, shortness of breath, racing heart, drop in blood pressure and even life-threatening shock.
At the onset of any of these symptoms, which can occur even with initial use, immediate medical assistance is required.

Psychiatric disorders
Very rare: psychotic reactions, depression.

Nervous system disorders
Uncommon: central nervous disorders, such as headache, dizziness, insomnia, agitation, irritability or tiredness.

Eye disorders
Uncommon: visual disturbances. In this case, you must stop taking ibuprofen and inform your doctor.

Ear and labyrinth disorders
Rare: ringing in the ears (tinnitus).

Cardiac disorders
Very rare: palpitations, heart muscle weakness (heart failure), heart attack.

Vascular disorders
Very rare: high blood pressure (arterial hypertension).

Gastrointestinal disorders
Common: gastrointestinal complaints, such as heartburn, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation and minor gastrointestinal blood loss, which may cause anaemia in exceptional cases.

Uncommon: stomach/duodenal ulcers (peptic ulcers), sometimes with bleeding and perforation, inflammation of the mouth lining with ulceration (ulcerative stomatitis), worsening of colitis or Crohn's disease
Inflammation of the stomach lining (gastritis).

Very rare: inflammation of the gullet (oesophagitis) and pancreas (pancreatitis). Formation of membrane like constrictions in the small and large intestine (intestinal, diaphragm-like strictures).

At the onset of relatively severe pain in the upper abdomen, blood vomiting, blood in stools and/or black stools, you must stop Ibu AIWA 400 mg and tell a doctor immediately.

Hepatobiliary disorders
Very rare: liver dysfunction, liver damage, especially in long-term therapy, liver failure, acute liver inflammation (hepatitis).

During prolonged administration, liver function tests should be regularly monitored.

Skin and subcutaneous tissue disorders
Very rare: severe skin reactions, such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome); hair loss (alopecia).

Not known: A severe skin reaction known as DRESS syndrome may occur. The symptoms of DRESS include skin rash, fever, swollen lymph nodes and an increase in eosinophils (a form of white blood cell).

A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Ibu AIWA 400 mg if you develop these symptoms and seek medical attention immediately. See also section 2.

Skin becomes sensitive to light.

In exceptional cases, severe skin infections and soft-tissue complications may occur during chickenpox (varicella infection) (see also "Infections and infestations").

Renal and urinary disorders
Very rare: increased fluid retention in body tissue (oedema), especially in patients with high blood pressure or impaired kidney function; nephrotic syndrome (fluid accumulation within the body [oedema]) and severe proteinuria (protein excretion in the urine); inflammatory kidney disease (interstitial nephritis), which may be associated with acute kidney dysfunction.

Damage to kidney tissue (papillary necrosis) and increased uric acid concentrations in the blood may also occur.

Reduced urine output, fluid accumulation within the body (oedema) and malaise (generally feeling ill) can be signs of kidney disease or even kidney failure.
If the above symptoms should appear or get worse, you must stop Ibu AIWA 400 mg and contact your doctor immediately.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibu AIWA 400 mg

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ibu AIWA 400 mg contains
The active substance is: ibuprofen.

Each film-coated tablet contains 400 mg ibuprofen.

The other ingredients are:
Maize starch, potato starch, carboxymethyl starch sodium (type A) (Ph.Eur.), pregelatinised starch (from maize), colloidal anhydrous silica, magnesium stearate (Ph.Eur.), macrogol (6000), hypromellose, talc, titanium dioxide (E171).

What Ibu AIWA 400 mg looks like and contents of the pack
Ibu AIWA 400 mg film-coated tablets are white, oblong film-coated tablets with score lines on both sides.

Pack of 20 film-coated tablets
Pack of 50 film-coated tablets (N3)

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Made in Germany.

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This medicine is available from pharmacies only.

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