Package leaflet: Information for the patient

Ibuprofen Zentiva 400 mg film-coated tablets
Ibuprofen Zentiva 600 mg film-coated tablets
Ibuprofen Zentiva 800 mg film-coated tablets

ibuprofen

[For medicinal products **not subject** to medical prescription - OTC]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days with fever or migraine headache or after 5 days with pain. You must talk to a doctor if your child or adolescent does not feel better or feels worse after 3 days.

[For medicinal products **subject** to medical prescription - Rx]
Read all of this leaflet carefully before you start taking 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, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

[To be completed nationally]

What is in this leaflet

1. What <Product name> is and what it is used for

[<Product name> 400 mg, 600 mg and 800 mg film-coated tablets]
<Product name> contains ibuprofen, which belongs to a group of medicines called non-steroidal antiinflammatory drugs (NSAID). These medicines work by reducing pain, fever and inflammation.

<Product name> is used for the treatment of rheumatic conditions such as arthritic diseases (e.g. rheumatoid arthritis, osteoarthritis), non-articular rheumatic conditions or other muscular and joint disorders, and soft tissue injuries.

<Product name> 400 mg and 600 mg is recommended for adults and adolescents from 40 kg bodyweight (over 12 years).

<Product name> 800 mg is recommended for adults only.

[<Product name>400 mg film-coated tablets]
In addition, <Product name> 400 mg is used for short-term symptomatic treatment of mild to moderate pain, such as headaches (including migraine headache), backaches and pains of muscles and joints, toothache, period pain and acute pain and fever associated with the common cold.

2. What you need to know before you take <Product name>

Do not take <Product name>
- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had allergic reactions such as asthma, runny nose, itchy skin rash or swelling of the lips, face, tongue, or throat after you have taken medicines containing acetylsalicylic acid or other NSAIDs.
- if you have or have ever had a recurrent ulcer or bleeding in the stomach or small intestine (duodenum) with two or more of these episodes in the past.
- if you have ever had gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- if you have a disorder of blood formation or disorder of blood clotting.
- if you have severe heart, liver or kidney failure.
- if you are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake).
- if you have any active bleeding (including in the brain).
- if you are in the last 3 months of pregnancy (see section “Pregnancy, breast-feeding and fertility”).

Warnings and precautions
Talk to your doctor or pharmacist before taking <Product name>:
- if you have kidney or liver problems.
- if you have asthma.
- if you have hay fever, nasal polyps or chronic obstructive respiratory disorders due to an increased risk of allergic reactions.
- if you are also taking drugs which could increase the risk of ulceration or bleeding (see Other medicines and <Product name> below).
- if you have heart problems including heart failure, angina (chest pain), or if you have ever had a heart attack, bypass surgery, peripheral artery disease (poor circulation in arms, legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- if you have systemic lupus erythematosus (immunity system disorder) or mixed connective tissue disease (the risk of aseptic meningitis).
- if you have inflammatory ulcerous disease of digestive tract such as Crohn´s disease or ulcerative colitis.
- if you have problems with normal blood clotting mechanism.
- if you have just had major surgery.
- if you are in the first six months of pregnancy.
- if you are breast-feeding (see section “Pregnancy, breast-feeding and fertility”).
- if you have an infection - please see heading “Infections” below.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately <Product name> and contact immediately your doctor or medical emergencies if you notice any of these signs.

Elderly
If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal.

Ulcers, perforation and bleeding in the stomach or intestines
Bleeding, ulceration or perforation in the stomach or intestines may occur without any warning signs even in patients who have never had such problems before. It may be life-threatening.

The risk of bleeding in the stomach or intestines, ulceration or perforation generally increases with higher doses of ibuprofen. It is also higher in elderly, see the "Elderly" section under "How to take <Product name>" for more information. The risk also increases if certain other medicines are taken at the same time as ibuprofen (see "Other medicines and <Product name>").

Patients who have ever had stomach problems, especially elderly, should be aware of any unusual symptoms from the stomach or intestines and report them at once to your doctor.

If bleeding or ulceration of the digestive tract occurs, the ibuprofen-treatment must be stopped.

Effects on the heart and brain
Antiinflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment. Any risk is more likely with high doses and prolonged treatment.

Skin reactions
Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using <Product name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Effects on the kidneys
Ibuprofen may cause problems with kidney function even in patients who have not had kidney problems before. This may result in swelling of the legs and may even lead to heart failure or high blood pressure in predisposed individuals.
Ibuprofen may cause kidney damage especially in patients who already have kidney, heart or liver problems, or are taking diuretics or ACE inhibitors, as well as in the elderly. Stopping Ibuprofen however generally leads to recovery.

Infections
<Product name> may hide signs of infections such as fever and pain. It is therefore possible that <Product name> 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 chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Other precautions
Prolonged use of any type of painkiller for headaches can make them worse. If you experience frequent or daily headaches despite (or because of) the regular use of headache medication, consult your doctor before taking another painkiller. The treatment should be discontinued if medication overuse headache (MOH) is diagnosed.

Do not take <Product name> if you are planning a pregnancy. Consult your doctor first. See also section "Pregnancy, breast-feeding and fertility".

Children and adolescents
<Product name> 400 mg and 600 mg is not to be used in adolescents weighing less than 40 kg or children below 12 years of age.
<Product name> 800 mg is not to be used in children and adolescents under 18 years of age.

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
<Product name> may affect or be affected by some other medicines. For example:

- medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- other NSAIDs or acetylsalicylic acid since these medicines may increase the risk of gastrointestinal ulcers or bleeding
- methotrexate (used to treat cancer and auto-immune diseases) since ibuprofen may enhance the effect of this medicine
- digoxin (for treatment of various heart conditions) since the effect of digoxin may be enhanced
- phenytoin (used in prevention of the occurrence of epileptic seizures) since ibuprofen may enhance the effect of this medicine
- lithium (used to treat depression and mania) since ibuprofen may enhance the effect of this medicine
- potassium-sparing diuretics since this may lead to hyperkalaemia (high potassium levels in the blood)
- cholestyramine (used in the treatment of high cholesterol) since the effect of ibuprofen may be decreased. The medicinal products should be administered with at least one-hour interval.
- aminoglycosides (medicines against certain types of bacteria) since ibuprofen may decrease the elimination of aminoglycosides, their co-administration may increase the risk of toxicity
- SSRIs (medicines against depression) such as paroxetin, sertralin, citalopram as these may increase the risk of gastrointestinal bleeding
- moclobemide (RIMA – a medicine to treat depressive illness or social phobia) since the effect of ibuprofen may be enhanced
- ciclosporine, tacrolimus (for immuno-suppression after organ transplant) since kidney damage may occur
- zidovudine (used to treat patients with HIV)) since the use of this medicine may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
- ritonavir (used to treat patients with HIV) since ritonavir may raise the concentration of ibuprofen
- mifepristone since ibuprofen may reduce the effect of this medicine
- probenecid or sulfinpyrazone (for treating gout) since the excretion of ibuprofen may be delayed
- quinolone antibiotics since the risk for convulsions may be increased
- sulphonylureas (to treat type 2 diabetes) since the effect of these medicines may be enhanced
- corticosteroids (used against inflammations) since these medicine may increase the risk of gastrointestinal ulcers or bleeding
- bisphosphonates (used in osteoporosis, Paget’s disease and to reduce high blood calcium levels) since these may increase the risk of gastrointestinal ulcers or bleeding
- oxpentifylline ((pentoxifylline) used in the treatment of circulatory disease of the arteries of the legs or arms) since these may increase the risk of gastrointestinal ulcers or bleeding
- baclofen (a muscle relaxant) since the toxicity of baclofen may be enhanced
- CYP2C9 inhibitors since concomitant administration of ibuprofen with CYP2C9 inhibitors (voriconazole, fluconazole) may increase the exposure to ibuprofen (CYP2C9 substrate).

<Product name> with food and alcohol
If you have a sensitive stomach, it is recommended to take this medicine together with food.
Avoid alcohol since it may enhance the side effects of this medicine, especially those affecting the stomach, intestines or brain.

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

Pregnancy
Do not take <Product name> if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.
You should not take <Product name> during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.
If taken for more than a few days from 20 weeks of pregnancy onward, <Product name> can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding
Ibuprofen passes into breast milk but is not likely to have an effect on the breast-feeding child when used for short-term treatment. If, however, longer treatment is prescribed, early weaning should be considered.

Fertility
<Product name> may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines
Ibuprofen generally has no adverse effects on the ability to drive or operate machinery. However, at high dosage side effects such as tiredness and dizziness may occur and the ability to drive a car or operate machinery may be impaired. This effect is potentiated by simultaneous consumption of alcohol.

<Product name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take <Product name>

[For medicinal products **not subject** to medical prescription - OTC]
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.

[For medicinal products **subject** to medical prescription - Rx]
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.

How to take <Product name>

Swallow the tablet with a glass of water. Do not crush, chew or suck the tablet to avoid stomach or throat irritation. If you have a sensitive stomach, it is recommended to take this medicine together with food.

How much to take of <Product name>
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). In long-term treatment of rheumatic conditions, a low maintenance dose should be the aim.

The ibuprofen dose in adolescents depends on the patient's age and body weight.
The maximum single dose should not be greater than 800 mg of ibuprofen for adults or 600 mg of ibuprofen for adolescents.

[For medicinal products **not subject** to medical prescription - OTC]
Adults: You must talk to a doctor if you do not feel better or if you feel worse after 3 days with a fever or migraine headache or after 5 days with pain.

Adolescents: If in adolescents this medicinal product is required for 3 days, or if symptoms worsen a doctor should be consulted.

<Product name> 400 mg and 600 mg is not to be used in adolescents weighing less than 40 kg or children below 12 years of age.
<Product name> 800 mg is not to be used in children and adolescents under 18 years of age.

Higher doses than those recommended can pose serious risks. Do not use different types of pain-relieving medicines at the same time without a doctor's prescription.

The recommended dose is:

Rheumatic diseases
Adults:
Maximum daily dose: 2 400 mg.
The dose should be taken as followed:
One tablet of 400 mg or one tablet of 600 mg, 3 times a day. Allow at least 4-6 hours between doses. Lower doses may be prescribed by your doctor. Due to the nature and severity of your condition, the doctor may increase your medication to one tablet of <Product name> 800 mg, taken 3 times a day.

Adolescents from 40 kg (over 12 years of age):
The daily dose is 20 mg/kg to a maximum of 40 mg/kg of bodyweight divided in 3 to 4 doses of 400 mg or 600 mg tablet. The maximum daily dose is 2 400 mg.

Mild to moderate pain and acute pain and fever
Adults and adolescents from 40 kg (older than 12 years of age):
Maximum daily dose:1 200 mg.
The dose should be taken as followed:
One tablet taken as a single dose or up to 3 times a day when needed. Allow at least 4 to 6 hours between doses.

Migraine headache
Maximum daily dose:1 200 mg.
The dose should be taken as followed:
One tablet of 400 mg taken as required, 1 to 3 times a day. Allow at least 4 to 6 hours between doses. More than 400 mg at a time does not provide better pain relief.

Menstrual pain
Adults and adolescents from 40 kg (over 12 years of age):
Maximum daily dose:1 200 mg.
The dose should be taken as followed:
One tablet of <Product name> 400 mg at the first sign of menstruation problems, 1-3 times a day.
Allow at least 4 to 6 hours between doses.

Elderly
If you are elderly, you should always consult your doctor before using <Product name>.If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal. Your doctor will advise you accordingly.

Reduced liver or kidney function
If you have reduced kidney or liver function, always consult a doctor before using <Product name>.

If you take more <Product name> than you should
If you have taken more <Product name> than you should, or if children have taken medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses loss of consciousness, convulsions (mainly in children), slow heartbeat, weakness and dizziness (fall in blood pressure), blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

If you forget to take <Product name>
If you forget to take a dose, take it as soon as you can, except if there is less than four hours remaining until the time for the next dose.

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

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.

Undesirable effects are more likely with higher doses and longer duration of treatment.

Stop taking <Product name> and seek immediate medical advice if any of the following symptoms occur:
- Angioedema (may affect up to 1 in 10 000 people) with symptoms such as:
  - swelling of the face, tongue or throat
  - difficulty swallowing
  - hives and difficulty in breathing.
- Black tarry stools or blood-stained vomit (may affect up to 1 in 10 people).
- Serious skin and mucous membrane changes such as epidermal necrolysis and/or erythema multiforme have been reported (a very rare side effect). In addition, a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). Frequency not known (frequency cannot be estimated from the available data).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment

(acute generalised exanthematous pustulosis). Frequency not known (frequency cannot be estimated from the available data).
- Blurred vision or other eye problems such as sensitivity to light, vision loss (may affect up to 1 in 1 000 people).
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis) (may affect up to 1 in 10 000 people).

Other side effects which may occur are listed below in groups according to the frequency:

Very common (may affect more than 1 in 10 people):
- Heartburn, abdominal pain, indigestion.
- Disturbances in the digestive tract, such as diarrhoea, feeling sick, vomiting, wind, constipation.

Common (may affect up to 1 in 10 people):
- Digestive tract ulcer with or without perforation.
- Bowel inflammation and worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease) and complications of diverticula of the large bowel (perforation or fistula).
- Microscopic bleeding from the intestine which may result in anaemia.
- Mouth ulcers and inflammation.
- Headache, sleepiness, vertigo, dizziness, fatigue, agitation, insomnia and irritability.

Uncommon (may affect up to 1 in 100 people):
- Inflammation of the stomach lining.
- Kidney problems including development of oedema, inflammation of the kidneys and kidney failure.
- Runny nose, asthma.
- Rash, increased sensitivity of the skin to sun.
- Over-sensitivity reaction such as hives, itching.

Rare (may affect up to 1 in 1 000 people):
- Depression, confusion, hallucinations.
- Lupus erythematosus syndrome.
- Increase of blood urea nitrogen and other liver enzymes, decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation and prolonged bleeding time, decrease of serum calcium and increase in serum uric acid values.

Very rare (may affect up to 1 in 10 000 people):
- Unpleasant awareness of heart-beat, heart failure or heart attack or high blood pressure.
- Disorders of blood cell formation (with symptoms like: fever, sore throat, surface mouth ulcers, flu- like symptoms, severe fatigue, nasal and skin bleeding).
- Ringing or buzzing in the ears.
- Inflammation of the oesophagus or pancreas.
- Narrowing of the bowel.
- Liver damage causing yellowish discolouration of the skin or whites of the eyes and fluid retention in body.
- Inflammation of the brain membrane (without bacterial infection).
- Damage of the kidney tissue.
- Hair loss.
- Psychotic reactions.
- Inflammation of the blood vessels.

- Ibuprofen may hide signs and symptoms of infections, worsening of infections or complications of infections. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Not known (frequency cannot be estimated from the available data):
- Tingling of the hands and feet.
- Anxiety.
- Impaired hearing.
- General feeling of being unwell.
- Inflammation of the optic nerve which may cause vision problems.
- Low neutrophil count (a type of white blood cell).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Medicines such as <Product name> may be associated with a small increased risk of heart attack (myocardial infraction) or stroke. Water retention (oedema), high blood pressure and heart failure have been reported in association with NSAIDs.

<Product name> may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

During treatment with ibuprofen, some cases of meningitis (presenting as stiff neck, headache, nausea, vomiting, fever or disorientation) have been observed in patients with existing autoimmune disorders such as systemic lupus erythematosus or mixed connective tissue disease.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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

Store below 25 °C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton. 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 <Product name> contains
- The active substance is ibuprofen.
  Each 400 mg tablet contains 400 mg of ibuprofen.
  Each 600 mg tablet contains 600 mg of ibuprofen.

Each 800 mg tablet contains 800 mg of ibuprofen.

- The other ingredients are
  Tablet core: cellulose, microcrystalline; croscarmellose sodium; hypromellose; stearic acid; silica, colloidal anhydrous; magnesium stearate.
  Coating for 400 mg tablet: hypromellose; macrogol; talc; titanium dioxide (E171).
  Coating for 600 mg tablet: hypromellose; macrogol; talc; titanium dioxide (E171).
  Coating for 800 mg tablet: hypromellose; macrogol; talc; titanium dioxide (E171); iron oxide yellow (E172).

What <Product name> looks like and contents of the pack

<Product name> 400 mg film-coated tablet: white to off-white rounded film-coated tablets with diameter 12 mm.
<Product name> 600 mg film-coated tablet: white to off-white oblong (17 x 10 mm) film-coated tablets.
<Product name> 800 mg film-coated tablet: light yellow to beige oblong (20 x 10 mm) film-coated tablets.

The tablets are packed into PVC/Alu blisters.

Pack sizes:
<Product name> 400 mg: 10, 12, 20, 24, 30, 36, 40, 48, 50, 100, 250 film-coated tablets
<Product name> 600 mg: 10, 20, 30, 40, 50, 100, 250 film-coated tablets
<Product name> 800 mg: 10, 20, 30, 100 film-coated tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:
400 mg tablet
Slovakia: Ibuprofen Zentiva ks
Denmark, Sweden, Finland, Romania, Iceland, Norway: Ibuprofen Zentiva
Austria: Zenalgin
Spain: Ibuprofeno Zentiva ks

600 mg tablet
Denmark, Sweden, Finland, Iceland, Norway: Ibuprofen Zentiva
Austria: Zenalgin

800 mg tablet
Sweden, Finland: Ibuprofen Zentiva
Austria: Zenalgin

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