

## Package leaflet: Information for the user

### Ibuprofen Zentiva 400 mg film-coated tablets

ibuprofen

**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 your doctor if you do not feel better or if you feel worse:
  - After 3 days for adolescents
  - After 3 days for fever or after 4 days for pain in adults.

#### What is in this leaflet

1. What Ibuprofen Zentiva is and what it is used for
2. What you need to know before you take Ibuprofen Zentiva
3. How to take Ibuprofen Zentiva
4. Possible side effects
5. How to store Ibuprofen Zentiva
6. Contents of the pack and other information

#### 1. What Ibuprofen Zentiva is and what it is used for

Ibuprofen Zentiva contains ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

It is indicated in adults and adolescents weighing over 40 kg (that is aged from 12 years), for short-term treatment of fever and/or pain such as headache, flu-like symptoms, toothache, and period pain.

It is indicated in adults, after at least one doctor has been consulted, for the treatment of mild to moderate migraine attacks, with or without aura.

#### 2. What you need to know before you take Ibuprofen Zentiva

##### Do not take Ibuprofen Zentiva

- 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, shortness of breath, or asthma, runny nose, itchy skin rash or swelling of the lips, face, tongue, or throat or hives after previously taking medicines containing ibuprofen, acetylsalicylic acid or similar painkillers (NSAIDs);
- if you are in the last three months of pregnancy (see below);
- if you have a history of gastrointestinal bleeding or ulcers in connection with previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs);
- if you have or have ever had a recurrent ulcer or bleeding in the stomach or small intestine, bleeding in the brain or other ongoing bleeding;
- if you have serious liver failure;
- if you have serious kidney failure;

- if you have serious heart failure;
- if you have systemic lupus erythematosus (the most common type of lupus).
  - in children under 12 years of age or in adolescents under 40 kg body weight, as this dose strength is not suitable due to the higher active substance content.
  - if you are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake);

If in doubt, ask to your doctor or pharmacist for advice.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Ibuprofen Zentiva.

This medicine has anti-inflammatory properties at high doses (above 1,200 mg/day), and may cause side effects seen with non-steroidal anti-inflammatory drugs (NSAIDs), sometimes serious.

Anti-inflammatory/painkiller medicines such as ibuprofen are likely to be associated with a slightly increased risk of heart attack or stroke, particularly when used in high doses. Do not exceed the recommended dose or duration of treatment.

Talk to your doctor or pharmacist before taking Ibuprofen Zentiva 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 the arms, legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”);
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- if you suffer or have suffered from asthma or allergic reactions, you may experience shortness of breath; The allergic reactions can occur as asthma attacks (so-called analgesic asthma), Quincke’s oedema or hives. Stop immediately Ibuprofen Zentiva and contact immediately your doctor or medical emergencies if you notice any of these signs.

### **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 Ibuprofen Zentiva and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

### **Infections**

Ibuprofen Zentiva can mask signs of infection such as fever and pain. Therefore, it is possible that Ibuprofen Zentiva may delay appropriate treatment of the infection, which may lead to an increased risk of complications. This has been observed in bacterial pneumonia and bacterial skin infections associated with chickenpox. If you take this medicine during an infection and your infection symptoms persist or worsen, consult a doctor immediately.

### **Special warnings**

Elderly are at greater risk of side effects, particularly bleeding in stomach and intestine, ulcers and perforations. Their kidney, liver and heart function must be closely monitored. Dosage should be kept as low as possible for the shortest period necessary to relieve symptoms.

There is a risk of kidney failure in dehydrated adolescents.

### **Before using this medicine, consult your doctor in case of:**

- history of asthma associated with chronic rhinitis, chronic sinusitis or polyps in the nose. Administration of this medicine may lead to an asthma attack, particularly in certain patients who

are allergic to acetylsalicylic acid (aspirin) or to a non-steroidal anti-inflammatory drugs (see section “Do not take Ibuprofen Zentiva”);

- clotting disorders or anticoagulant treatment. This medicine can cause serious gastrointestinal symptoms;
- a history of gastrointestinal diseases (hiatus hernia, bleeding in stomach and intestine, previous stomach or duodenal ulcers);
- heart, liver or kidney disease;
- chickenpox. This medicine is not recommended because of serious skin infections in exceptional cases;
- simultaneous treatment with other medicines that increase the risk of peptic ulcer or bleeding, for example oral corticosteroids, antidepressants (SSRIs, i.e. selective serotonin reuptake inhibitors), medicines that prevent the formation of blood clots such as aspirin or anticoagulants such as warfarin. If this applies to you, talk to your doctor before taking Ibuprofen Zentiva (see “Other medicines and Ibuprofen Zentiva”);
- simultaneous treatment with methotrexate at doses above 20 mg per week or with pemetrexed (see section “Other medicines and Ibuprofen Zentiva”).
- if you are trying to become pregnant.

#### **During treatment, in case of:**

- sight problems, inform your doctor;
- stomach or intestine bleeding (discharge of blood through the mouth or in the stools, black stools), stop the treatment and contact a doctor or emergency medical service immediately;
- signs resembling a burn appear on the skin or mucous membranes (redness with bullae or blisters, ulcerations), stop the treatment and contact a doctor or emergency medical service immediately;
- signs suggesting an allergy to this medicine, in particular an asthma attack or sudden swelling of the face and neck (see section “possible side effects” ), stop the treatment and contact a doctor or emergency medical service immediately.

#### **Other medicines and Ibuprofen Zentiva**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines cannot be used at the same time, while others require specific changes (for example in dosage).

#### **This medicine contains a non-steroidal anti-inflammatory drug (NSAID), ibuprofen.**

You must not take other medicines containing NSAIDs (including selective cyclooxygenase-2 inhibitors) and/or acetylsalicylic acid (aspirin) at the same time as this medicine. Carefully read the package leaflets of any other medicines you are taking to make sure they do not contain NSAIDs and/or acetylsalicylic acid (aspirin).

This medicine must not be taken in combination with mifamurtide.

Always tell your doctor or pharmacist if you are taking any of the following medicines in addition to Ibuprofen Zentiva:

- aspirin (acetylsalicylic acid) or other non-steroidal anti-inflammatory drugs, including selective cyclooxygenase-2 inhibitors as this may increase the risk of stomach and intestinal ulcers or bleeding;
- corticosteroids, glucocorticoids; this may increase the risk of stomach and intestinal ulcers or bleeding;
- lithium (used for mental illness treatment); as the effect of lithium may be increased;
- methotrexate (used in chemotherapy); as the effect of methotrexate may be increased;
- certain antidepressants (selective serotonin reuptake inhibitors); as this can increase the risk of stomach/intestinal bleeding;

- pemetrexed (chemotherapy treatment);
- methotrexate (a medicine used to treat cancer or rheumatism), as the effect of methotrexate may be increased;
- medicines used to treat pain and inflammation (such as acetylsalicylic acid, unless low doses have been advised by the doctor);
- ciclosporin, tacrolimus (used in rheumatoid arthritis); (immunosuppressive medicines), as this may cause kidney damage;
- cardiac glycosides such as digoxin, (used in many heart conditions), as their effects may be increased.
- mifepristone (a medicine used to terminate pregnancy). Ibuprofen Zentiva should not be used within 8-12 days after taking mifepristone, as the effect of mifepristone may be reduced;
- zidovudine (a medicine for the treatment of AIDS) because with the use of Ibuprofen Zentiva, there is an increased risk of haemarthrosis (bleeding into a joint cavity) and haematomas (clotted blood) in haemophiliac (blood clotting disease) patients with HIV; In HIV-positive haemophilia patients (“haemophiliacs”), the risk of joint bleeding (haemarthrosis) or bleeding leading to swelling may be increased.
- quinolones (antibiotics), as these can increase the risk of seizures;
- nicorandil (used to treat angina);
- cobimetinib (anti-cancer medicine);
- tenofovir disoproxil (used to treat hepatitis B and AIDS);
- mixed adrenergic-serotonergic medicines;
- pentoxifylline (used to treat muscle pain) ;
- voriconazole and fluconazole (CYP2C9 inhibitors) against fungal infections, as the effect of ibuprofen may be increased. Reduction of the ibuprofen dose should be considered, particularly when high dose ibuprofen is co-administered with either voriconazole or fluconazole.

Ibuprofen Zentiva may affect or be affected by certain other medicines. For example:

- anticoagulant medicines (medicines used to thin the blood (such as warfarin)), as ibuprofen can increase the blood-thinning effect of these medicines;
  - potassium-sparing diuretics, as this can cause hyperkalaemia (too much potassium in the blood);
  - medicines for high blood pressure and diuretic tablets, as ibuprofen can weaken the effect of these medicines, possibly resulting in an increased risk to the kidneys;

Some other medicines may also affect or be affected by treatment with Ibuprofen Zentiva. You should therefore always ask your doctor or pharmacist for advice before using Ibuprofen Zentiva with other medicines.

### **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 you have taken this medicine while pregnant, talk to your gynaecologist immediately, so that you can be offered appropriate monitoring if necessary.

Do not take this medicine 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 Ibuprofen Zentiva 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, Ibuprofen Zentiva 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**

Do not take this medicine during breast-feeding as it passes into breast milk.

#### **Fertility**

This medicine, like all non-steroidal anti-inflammatory drugs (NSAIDs), may impair fertility in women and cause difficulties in becoming pregnant, which are reversible on discontinuation of treatment. Tell your doctor if you are planning a pregnancy or if you are having difficulty conceiving.

#### **Driving and using machines**

In rare cases, taking this medicine may cause dizziness and sight problems. If you have these symptoms do not drive or use machines.

#### **Ibuprofen Zentiva contains sodium**

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

#### **Ibuprofen Zentiva contains isomalt**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take Ibuprofen Zentiva**

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

The lowest effective dose should be used for the shortest duration required to relieve symptoms. If you have an infection, consult a doctor immediately if the symptoms (such as fever and pain) persist or get worse (see section 2).

#### **Method and route of administration**

- Oral route. Short-term use.
- Swallow the tablet without chewing, with a large glass of water.
- The tablets should preferably be taken with a meal. If Ibuprofen Zentiva is taken during or shortly after a meal, the onset of action may be delayed. If this is the case for you, do not take more than the dose recommended and do not reduce the specified dosing interval.

The recommended dose is:

<b>Body weight (age)</b>	<b>Single dose</b>	<b>max. daily dose</b>
40 kg or more (Adolescents from 12 years and adults)	1 film-coated tablet (corresponding to 400 mg ibuprofen)	3 film-coated tablets (corresponding to 1200 mg ibuprofen)

### **Duration of treatment**

- Adults and adolescents: If treatment needs to be continued for more than 3 days or if the symptoms get worse, consult a doctor.
- If the pain persists for more than 5 days, or if the fever or migraine persists for more than 3 days, or if it gets worse, or if another disorder develops, inform your doctor. For a migraine attack, the duration of treatment should not exceed 3 days. If symptoms persist or get worse, or if new symptoms appear, ask your pharmacist or doctor for advice.

If you feel that the effect of Ibuprofen Zentiva, is too strong or too weak, consult your doctor or pharmacist.

### **If you take more Ibuprofen Zentiva than you should**

If you have taken more Ibuprofen Zentiva 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), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur.

Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, high levels of potassium, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure, reduced breathing and blue-red discoloration of the skin and mucous membranes (cyanosis).

### **If you forget to take Ibuprofen Zentiva**

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

If you have any further questions about taking 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 list of side effects may occur if you receive short-term treatment with ibuprofen. For long-term treatment or if your doctor prescribes a higher dose, more side effects may occur than those described below.

Side effects can be reduced by using the lowest effective dose for the shortest period necessary for controlling symptoms. You may experience one or more of the known side effects known of NSAIDs (see below). If this is the case or if you have any concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly patients have a higher risk of developing problems due to side effects when taking this medicine.

### **STOP taking this medicine and tell your doctor immediately if you get any of the following side effects:**

- **Signs of gastrointestinal bleeding** such as severe abdominal pain, black stools, vomiting blood or dark particles that resemble coffee grounds in appearance.
- **Signs of very rare but serious allergic reactions** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, rapid heartbeat, drop in blood pressure leading to shock. This can happen even when you first take this medicine.

- 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] (Very rare - may affect up to 1 in 10,000 people).
- Widespread rash, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cells) (DRESS syndrome) (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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis) (Not known - frequency cannot be estimated from the available data).

**If any of the following side effects occurs or gets worse, or if you notice any effects not listed in this leaflet, please tell your doctor.**

**Uncommon** (may affect up to 1 in 100 people):

- allergic reactions accompanied by itching and hives, as well as asthma attacks and breathing difficulties. you should stop taking Ibuprofen Zentiva and tell your doctor immediately.
- headaches
- abdominal pain, nausea and (indigestion)
- various rashes

**Rare** (may affect up to 1 in 1,000 people):

- diarrhoea, flatulence, constipation and vomiting

**Very rare** (may affect up to 1 in 10,000 people):

- problems in the production of blood cells; the first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, extreme fatigue, nosebleeds and bleeding into the skin. In these cases, you should stop treatment immediately and consult a doctor. Avoid self-medication with painkillers or fever-reducing drugs (antipyretics).
- severe allergic reactions, the signs of which may be: swelling of the face, tongue and throat, shortness of breath, increased heart rate, low blood pressure, severe shock. If any of these symptoms occur, which can happen even when the product is used for the first time, immediate medical attention is required.
- aseptic meningitis.
- peptic ulcer, perforation, gastrointestinal haemorrhage, tarry black stools, vomiting of blood or dark particles resembling coffee grounds, ulcerative stomatitis, gastritis.
- liver damage (the first sign may be skin discoloration).
- 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) and Lyell's syndrome.
- kidney injury, papillary necrosis specifically during long-term treatment associated with an increase in uraemia and oedema.

**Not known** (frequency cannot be estimated from the available data):

- dizziness
- sight problems
- heart failure, swelling
- high blood pressure
- aggravation of colitis and Crohn's disease
- hepatitis, increased transaminases.
- infectious complication of the skin and soft tissues during chickenpox.

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). If you develop these symptoms, stop using Ibuprofen Zentiva and consult a doctor immediately. See also section 2.
- sensitivity of the skin to light.
- impaired hearing.
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

In all these cases, you should inform your doctor.

In exceptional cases, changes in the liver or blood count (decrease in white blood cells or red blood cells) have been observed, which may be serious.

Medicines like Ibuprofen Zentiva may be associated with a slightly increased risk of heart attack (“myocardial infarction”) or stroke.

### **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 to:

Ireland  
HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Ibuprofen Zentiva**

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 Ibuprofen Zentiva contains**

- The active substance is ibuprofen.  
1 film-coated tablet contains 400 mg ibuprofen (as ibuprofen lysinate).
- The other ingredients are:  
Tablet core: sodium starch glycolate type A; povidone 30; magnesium stearate.  
Coating: The coating premix consisting of: hypromellose; isomalt; calcium carbonate; stearic acid.

**What Ibuprofen Zentiva looks like and contents of the pack**

Ibuprofen Zentiva 400 mg film-coated tablet: white to off-white to yellowish, oval, approx. 9.1 x 19.1 mm film-coated tablets, thickness approx. 6.4 mm.

The tablets are packed into PVC/PVDC//Alu blisters.

Pack sizes:

12 film-coated tablets

**Marketing Authorisation Holder and Manufacturer**

Zentiva, k.s.

U kabelovny 130,

Dolní Měcholupy,

102 37 Prague 10,

Czech Republic

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

France: IBUPROFENE ZENTIVA FRANCE 400 mg, comprimé pelliculé

Ireland: Ibuprofen Zentiva 400 mg film-coated tablets

**This leaflet was last revised in March 2025.**