

## **Leaflet: information for the user**

### **PROFEN**

**Soft gelatin capsules - 400 mg**

*(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, even if these are 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, if the fever lasts for more than 3 days or the pain lasts for more than 3 days in adolescents or 5 days in adults.

#### **What is in this leaflet**

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

#### **1. What Profen is and what it is used for**

Ibuprofen, the active substance in this medicine, works by reducing pain and fever.

Profen is used in adults and adolescents over 12 years of age for symptomatic relief of occasional mild to moderate pain, such as headaches, dental, menstrual, muscle (contractures) or back pain (lumbago), as well as in feverish states.

You should see a doctor if it gets worse or does not get better, if the fever lasts for more than 3 days or the pain lasts for more than 3 days in adolescents or 5 days in adults.

## **2. What you need to know before taking Profen**

### **Do not take Profen if:**

- You are allergic to ibuprofen, other NSAIDs (e.g. acetylsalicylic acid, naproxen, etc.) or any of the other ingredients of this medicine (included in section 6). Reactions that indicate allergy could be: itchy rash, swelling of the face, lips or tongue, runny nose, respiratory distress or asthma.
- You have had a stomach or duodenal ulcer or bleeding or have had a perforation of the digestive apparatus.
- You vomit blood.
- You have black stools or bloody diarrhoea.
- You have severe liver or kidney problems.
- You suffer from bleeding or blood clotting disorders or are taking anticoagulants (medicines used to "fluidize" blood), if necessary, use anticoagulant medication at the same time, the doctor will perform tests for blood clotting.
- You suffer from severe heart failure.
- You are in the third trimester of pregnancy.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Profen if:

- You have had an ulcer, or you develop an ulcer, haemorrhage or perforation in the stomach or duodenum, which could manifest by severe or persistent abdominal pain and/ or black stools, or even without previous warning symptoms. This risk is greater when high doses and prolonged treatments are used, in patients with a history of peptic ulcer and in elderly patients.
- You have oedema (fluid retention).
- You suffer from asthma or any other respiratory disorder.

- You have or have had a heart disorder or have high blood pressure.
- You have kidney or liver disease, are over 60 years old or need to take the medication for a long time (more than 1-2 weeks), your doctor may need to check regularly.
- You have symptoms of dehydration, e.g. severe diarrhoea or vomiting, drink plenty of fluids and contact your doctor immediately, since ibuprofen in this particular case, could cause renal failure as a result of dehydration.  
In dehydrated adolescents there is a risk of deterioration of kidney function.
- You simultaneously take medications that alter blood clotting as oral anticoagulants, platelet antiaggregants of the acetylsalicylic acid type. You should also tell your doctor about the use of other medications that could increase the risk of such haemorrhages like corticosteroids and selective serotonin reuptake inhibitor antidepressants.
- You suffer from Crohn's disease (chronic disease in which the immune system attacks the intestine causing inflammation that usually causes bloody diarrhoea) or an ulcerative colitis because ibuprofen type medications can worsen these pathologies.
- You are being treated with diuretics (water pills) because your doctor should monitor the functioning of your kidney.
- You suffer from systemic lupus erythematosus (chronic disease that affects the immune system and can affect different vital organs, the nervous system, blood vessels, skin and joints) since aseptic meningitis can occur.
- You suffer from acute intermittent porphyria (metabolic disease that affects your blood and may cause symptoms such as reddish colour of urine, blood in urine or liver disease), to assess whether or not ibuprofen treatment is appropriate.
- You are being treated with ibuprofen because it may mask the fever, which is an important sign of infection, making it difficult to diagnose.
- You suffer from headaches after prolonged treatment you should not take higher doses of the medicine.
- Allergic reactions with this medicine may occur.
- The doctor will perform a stricter check if you receive ibuprofen after having major surgery.
- You have an infection, see the heading "Infections" below.

- It is advisable not to take this medicine if you have chickenpox.
- It is important that you use the smallest dose that relieves/ controls pain and you should not take this medication longer than necessary to control your symptoms.

### **Cardiovascular precautions**

Anti-inflammatory/ analgesic medications such as ibuprofen can be associated with a small increase in the risk of having a heart attack or stroke, especially when used in high doses. Do not exceed the recommended dose or duration of treatment.

Check with your pharmacist or your doctor before taking Profen if:

- **You have heart problems including heart failure, angina (chest pain) or if you have suffered a heart attack, bypass surgery, peripheral artery disease (circulation problems in the legs or feet due to narrowing or blockage of the arteries), or any type of stroke (including a “mini stroke” or transient ischemic accident “TIA”)**
- **You have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.**

This type of medication can also cause fluid retention, especially in patients with heart failure and/ or high blood pressure (hypertension).

### **Skin reactions**

Serious skin reactions have been reported in association with ibuprofen treatment. You should stop taking Profen and seek medical attention immediately, if you develop any 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.

### **Infections**

Ibuprofen can hide the signs of an infection, such as fever and pain. Consequently, Profen may delay the proper treatment of the infection, which may increase the risk of complications. This has been observed in bacterial pneumonia and bacterial skin infections

related to chickenpox. If you take this medicine while you have an infection and symptoms of the infection persist or worsen, see a doctor without delay.

### **Other medicines and Profen**

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

Profen can affect or be affected by other medicines. For example:

- Anticoagulant drugs (e.g. to treat clotting/coagulation problems, e.g. acetylsalicylic acid, warfarin, ticlopidine);
- Medicines that lower high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol medicines and angiotensin-II receptor antagonists such as losartan);
- Platelet antiaggregants (prevent the formation of thrombi or blood clots in the blood vessels) such as ticlopidine or aspirin (acetylsalicylic acid);
- Other NSAIDs such as aspirin;
- Corticosteroids such as cortisone and prednisolone;
- Selective serotonin reuptake inhibitors (used in depression);
- Lithium (medicine used to treat depression);
- Methotrexate (to treat cancer and inflammatory diseases). Your doctor may adjust the dose of this medicine.;
- Mifepristone (abortion inducer);
- Digoxin and cardiotonic glycosides (used in the treatment of heart disorders);
- Hydantoins such as phenytoin (used in the treatment of epilepsy);
- Sulfamides such as sulfamethoxazole and cotrimoxazole (used in the treatment of some bacterial infections);
- Diuretics (medicines used to increase urine elimination);
- Pentoxifylline (to treat intermittent claudication);
- Probenecid (used in patients with gout, or together with penicillin in infections);

- Quinolone group antibiotics such as norfloxacin;
- Sulfinpyrazone (for gout);
- Insulin and oral hypoglycemics (used to lower blood glucose);
- Tacrolimus or cyclosporine (used in organ transplants to prevent rejection);
- Antihypertensives: to lower high blood pressure;
- Thrombolytics (medications that dissolve thrombi);
- Zidovudine (medicine against AIDS virus);
- Aminoglycoside antibiotics such as neomycin;
- Herbal extracts: from the Ginkgo biloba tree;
- Baclofen (used to treat involuntary and persistent muscle contractions);
- Phenytoin (in the treatment of epilepsy);
- Ion exchange resins such as cholestyramine (used to lower blood cholesterol levels);
- Tacrine (used in the treatment of Alzheimer's disease);
- CYP2C9 inhibitors such as voriconazole and fluconazole.

Other medicines can also affect or be affected by the Profen treatment. You should therefore always consult your doctor or pharmacist before using Profen with other medicines.

Interaction with analytical tests:

If you are going to have any diagnostic tests (including blood tests, urine tests, skin tests using allergens, etc.), tell your doctor that you are taking or have recently taken this medicine, as it may alter the results.

**Profen with food, drink and alcohol**

It can be taken alone or with food. It is generally recommended to take it during meals or with milk to reduce the possibility of stomach upset.

You should not take ibuprofen with alcohol to avoid damaging your stomach.

Ibuprofen intake by patients who habitually consume alcohol (3 or more alcoholic drinks - beer, wine, liquor... a day) can cause them to bleed in their stomach.

**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 before taking this medicine.

### Pregnancy

Do not take ibuprofen 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 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 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.

### Breastfeeding

This medicine passes into breast milk but can be taken during breastfeeding if you use it at the recommended dose for the shortest possible period of time.

### Fertility

For patients of childbearing age, it should be noted that Profen type drugs have been associated with a reduced ability to conceive. Avoid taking this medicine if you are trying to become pregnant.

### **Driving and using machines**

If you experience dizziness, vertigo, impaired vision or other symptoms while taking this medicine, you must not drive or use dangerous machinery.

### **This medicine contains Allura red (E-129) and sorbitol (E-420)**

This medicine can cause allergic reactions because it contains Allura red (E-129). It may cause asthma, especially in patients allergic to acetylsalicylic acid.

This medicine contains 58.25 mg of sorbitol (E-420) per capsule.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to certain sugars, or have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disease in which the patient cannot break down fructose, consult your (or your child's) doctor before taking this medicine.

### **3. How to take Profen**

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

The recommended dose is:

- Adults and adolescents over 12 years old: Take one capsule (400 mg ibuprofen) every 6 -8 hours, if necessary. Do not take more than 3 capsules (1200 mg ibuprofen) in a 24 hour period.
- Patients with kidney, liver or heart failure: Reduce the dose and consult a doctor.
- Older than 65 years: The dosage should be established by the doctor, since a reduction in the usual dose may be necessary.

The lowest effective dose should be used for the shortest time necessary to relieve symptoms. If you have an infection, see a doctor promptly if symptoms (such as fever and pain) persist or worsen (see section 2).

### **Use in children and adolescents under 12 years of age**

Children under 12 cannot take this medicine because of the 400mg dose of ibuprofen. There are other presentations more suitable for this population.

#### How to take:

This medicine is taken orally.

Swallow the medicine with a little water.

Take the medicine with meals or with milk, especially if digestive problems are noted.

The medicine is taken subject to the onset of pain or fever. As these disappear, the medication must be stopped. In adolescents between 12 and 18 years of age, if the use of this medicine is required for more than 3 days or if the symptoms worsen, a doctor should be consulted.

In adults, if symptoms worsen, if fever persists for more than 3 days or pain persists for more than 5 days, a doctor should be consulted.

### **If you take more Profen than you should**

If you accidentally take or administer more medicine than you should, or if a child has accidentally ingested the medicine, immediately consult a doctor or call the emergency services, indicating the medicine and the amount used, or go to the nearest hospital to find out about the risk and ask for advice on the measures to be taken. It is recommended that you take the medicine's packaging and leaflet to the health professional.

Overdose symptoms may include stomach pain, nausea, vomiting (which may contain bloody sputum), headache, involuntary eye movements, ringing in the ears. At high doses intestinal bleeding, hypotension, metabolic acidosis, coma, symptoms of drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, chills and breathing problems have been reported.

If large quantities are ingested, activated charcoal should be administered. Stomach emptying should be considered if significant amounts have been ingested and during the 60 minutes following ingestion.

### **4. Possible side effects**

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

Side effects are more common in people over 65. The incidence of adverse effects is lower in short treatments and if the daily dose is below the maximum recommended dose.

### **STOP taking this medicine and seek medical help immediately if you have it:**

- **signs of intestinal bleeding**, such as: severe pain in the abdomen, black or tarry stools, vomiting blood or dark particles that look like ground coffee beans.
- **signs of a very rare but serious allergic reaction**, such as worsening of asthma, wheezing or altered breathing of unknown origin, swelling of the face, tongue or throat,

difficulty in breathing, racing of the heart, lowering of blood pressure leading to shock. These can occur even on the first use of this medicine.

- **severe skin reactions** such as rashes that cover the whole body, peeling, blistering or flaking of the skin.

**Tell your doctor if you experience the following side effects:**

**Common:** (may affect up to 1 in 10 people)

- stomach problems, such as heartburn, stomach pain and nausea, indigestion, diarrhoea, vomiting, flatulence (gas), constipation, and slight blood loss in the stomach and/or intestine that can cause anemia in exceptional cases.

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

- gastrointestinal ulcers, perforation or bleeding, inflammation of the mucous membrane of the mouth with ulceration, worsening of existing intestinal disease (ulcerative colitis or Crohn's disease), gastritis.
- disorders of the central nervous system, such as headache, dizziness, insomnia, agitation, irritability and tiredness.
- visual disturbances.
- various skin rashes.
- hypersensitivity reactions with hives and itching.

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

- tinnitus (ringing in the ears).
- increased concentration of urea in the blood, pain in the sides and/or abdomen, blood in the urine and fever, can be signs of damage to the kidneys (papillary necrosis).
- decrease in haemoglobin levels.

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

- oesophagitis, pancreatitis and diaphragm-type intestinal stenosis formation.
- heart failure, heart attack and swelling of face and hands (oedema).
- decreased amount of urine, swelling (oedema) and cloudy urine (nephrotic

syndrome), inflammatory kidney disease (interstitial nephritis) which can lead to acute kidney failure. If you experience any of the symptoms mentioned above or if you have a feeling of sadness, stop taking Profen and consult your doctor immediately as these may be the first signs of kidney damage or failure.

- psychotic reactions, depression.
- high blood pressure, vasculitis.
- palpitations.
- liver dysfunction (first symptoms may be discoloration of the skin), liver damage especially in prolonged treatment, liver failure, acute liver inflammation (acute hepatitis).
- problems in the production of blood cells. The first symptoms may be: fever, sore throat, mouth sores, flu-like symptoms, excessive tiredness, nose and skin bleeds and bruises of unknown origin. In these cases you should stop treatment immediately and consult your doctor. You should not self-medicate with analgesic drugs or drugs to reduce fever (antipyretic drugs).
- severe skin infections and soft tissue complications during chickenpox infection.
- the worsening of inflammation associated with infection (e.g. necrotising fasciitis) associated with the use of some analgesics (NSAIDs) has been described. If signs of infection appear or worsen, you should see a doctor immediately. It should be assessed whether antibiotic therapy is necessary.
- symptoms of aseptic meningitis with stiff neck, headache, nausea, vomiting, fever or disorientation have been observed during treatment with ibuprofen. It is more likely to affect patients with autoimmune disorders (e.g. SLE, mixed connective tissue disease). If this happens, contact your doctor immediately.
- severe forms of skin reactions such as skin rashes with redness and blistering (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, Lyell syndrome) and hair loss (alopecia).

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

- reactivity of the respiratory tract including asthma, bronchospasm or dyspnea.
- a severe skin reaction known as DRESS syndrome can occur. The symptoms of DRESS syndrome include: skin rash, swollen lymph nodes and elevated eosinophils

(a type of white blood cell).

- widespread red scaly rash, with bumps under the skin and blisters located mainly in skin folds, the trunk and upper extremities, accompanied by fever at the beginning of treatment (acute generalised exanthematous pustulosis). Stop taking Profen if you have these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light.

Medicines of this type may be associated with a slightly increased risk of heart attack or stroke. Prolonged bleeding time, oedema (fluid retention), high blood pressure and heart failure have also been observed in association with treatment with medicines such as Profen.

Based on experience with NSAIDs, cases of interstitial nephritis (disorder of the kidney), nephrotic syndrome (disorder characterized by protein in the urine and swelling of the body) and kidney failure (sudden loss of kidney function) cannot be excluded.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to the Pharmacovigilance Sector of the AKBPM (National Agency for Drugs and Medical Devices), via the email address: [farmakovigilanca@akbpm.gov.al](mailto:farmakovigilanca@akbpm.gov.al). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store de PROFEN**

Keep this medicine out of sight and reach of children.

Store below 30 °C.

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

Do not use this medicine if you notice signs of deterioration of the capsules.

### **6. Contents of the pack and other information**

#### **What Profen contains**

Each soft gelatin capsule contains 400 mg of ibuprofen as the active substance.

The other ingredients are:

*Core*: macrogol, potassium hydroxide, allura red (E-129) and purified water.

*Capsule*: gelatin, liquid sorbitol non-crystallising (E-420) and purified water.

### **What PROFEN looks like and contents of the pack**

Profen – Soft gelatin capsules are light red, oval-shaped transparent soft capsules.

Carton box containing 20 soft gelatin capsules.

### **Marketing Authorisation Holder**

Profarma sh.a

Rr. "Skënder Vila", Nd. 6, 1007

Tel.: +355 4 23 89 602

Tirana – Albania

[www.profarma.al](http://www.profarma.al)

### **Manufacturers**

**Profarma sh.a**

Rr. "Skënder Vila", Nd. 6, 1007

Tel.: +355 4 23 89 602

Tirana – Albania

### **HC Clover Productos y Servicios S.L.**

C/Alicante 8-10

28500 Arganda del Rey

Madrid -Spain

This leaflet was formulated in May 2023.