Package leaflet: Information for the patient

Ibuprofen Farmalider 200 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 have 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 in adolescents.
    - after 3 days in the treatment of fever and after 4 days in the treatment of pain in adults.

What is in this leaflet:

1. What Ibuprofen Farmalider is and what it is used for

Ibuprofen belongs to the group of medicines called nonsteroidal anti-inflammatory drugs (NSAID).

This medicinal product is used for the short-term symptomatic treatment of mild to moderate pain such as dental pain, headaches, or due to minor injuries and/ or fever in adolescents from 40 kg bodyweight (12 years of age and above) and adults.

2. What you need to know before you take Ibuprofen Farmalider

Do not take Ibuprofen Farmalider:

-If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
-If you have previously reacted with bronchospasm, asthma attacks, swelling of the nasal mucosa, angioedema or skin reactions following previous intake of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
-If you suffer from unclarified blood-formation disturbances.
-If you suffer from severe liver or severe kidney impairment.
-If you have previously had a gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
-In active or history of recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding in the gastrointestinal tract (two or more distinct episodes of proven ulceration or bleeding).
-If you suffer from severe heart failure.
-During the last 3 months of pregnancy (see section 2, Pregnancy, breast-feeding and fertility).
-Cerebrovascular or other active bleeding.
-Severe dehydration (from vomiting, diarrhoea, or insufficient fluid intake).

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen Farmalider.

Ibuprofen Farmalider should only be used after careful consideration of the risk/benefit ratio:
- in certain hereditary blood formation disorder (e.g. acute intermittent porphyria);
- in certain immune system disorders (systemic lupus erythematosus and mixed connective tissue disease).

Particularly careful medical surveillance is required in:
- gastrointestinal disorders or chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease);
- impaired kidney or liver function;
- dehydration;
- high blood pressure or heart failure;
- allergies (e.g. skin reactions to other agents, asthma, hay fever), nasal polyps, chronic swelling of the mucous membrane of the nose or chronic obstructive airways disease, as you are then at increased risk of experiencing a hypersensitivity reaction;
- recently undergone major surgery.
- have an infection – please see heading "Infections" below.

Infections

Ibuprofen Farmalider may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen Farmalider 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.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Other NSAIDs

The concomitant use of ibuprofen with NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Elderly

The elderly has an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. The elderly are at increased risk of the consequences of adverse reactions.

Gastrointestinal bleeding, ulceration and perforation

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.

The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, if you previously had an ulcer, particularly if complicated with bleeding or perforation, and in the elderly. You should commence treatment on the lowest dose available. Please talk to your doctor as a combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) could be considered. This also applies if you concomitantly take low dose of acetylsalicylic acid (aspirin), or other active substances likely to increase gastrointestinal risk.

If you previously had gastrointestinal toxicity, particularly when elderly, you should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment to your doctor. Caution should be advised if you concomitantly use medicines which could increase the risk of ulceration of bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-

reuptake inhibitors or anti-platelet agents such as acetylsalicylic acid (see Section 2, Other medicines and Ibuprofen Farmalider).

Treatment must be stopped and a doctor consulted when gastrointestinal bleeding or ulceration occurs during treatment with ibuprofen.

If you have / have had gastrointestinal disease (ulcerative colitis, Crohn´s disease), be careful when using NSAIDs, as your condition may get worse (see Section 4).

Skin reactions

Serious skin reactions have been reported in association with Ibuprofen Farmalider treatment. You should stop taking Ibuprofen Farmalider 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.

During chickenpox (varicella) it is advisable to avoid the use of ibuprofen.

Cardiovascular Precautions

Anti-inflammatory/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.

You should discuss your treatment with your doctor or pharmacist before taking ibuprofen if you:
- have heart problems including heart failure, angina pectoris (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of 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.

Renal effects

Ibuprofen may cause the retention of sodium, potassium and fluid in patients who have not previously suffered from renal disorders because of its effect on renal perfusion. This may cause oedema (fluid retention) or even lead to cardiac insufficiency or hypertension in predisposed patients. There have been reports of acute interstitial nephritis and renal toxicity. Patients at greatest risk are those with renal dysfunction, heart failure, hepatic dysfunction, those taking diuretics and ACE inhibitors and the elderly.
Discontinuation of NSAID treatment is generally followed by recovery to the pre-treatment state.

Allergic reactions

Severe acute hypersensitivity reactions (e.g. anaphylactic shock) have been observed in very rare cases. Therapy must be discontinued at the first signs of a hypersensitivity reaction after intake/administration of ibuprofen. Depending upon the symptoms, the required medical procedures must be initiated by trained personnel.

Other information

Ibuprofen, the active substance of this medicinal product may temporarily inhibit the blood-platelet function (thrombocyte aggregation). Patients with blood-coagulation disturbances should therefore be monitored carefully.

During prolonged use of ibuprofen, regular monitoring of liver enzymes, kidney function and the blood count is required.

You should drink enough during treatment, especially in the case of fever, diarrhea or vomiting.

NSAIDs such as ibuprofen may mask the symptoms of infection and fever.

Using NSAIDs in combination with alcohol can worsen adverse reactions caused by the active substance, especially those affecting the gastrointestinal tract or the central nervous system.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.
In general, habitual intake of painkillers, particularly a combination of several analgesic substances, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Children and adolescents

There is a risk of renal impairment in dehydrated adolescents.
This medicinal product should not be administered to adolescents less than 40 kg bodyweight or children under 12 years of age.

Other medicines and Ibuprofen Farmalider
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

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

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/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).

Some other medicines may also affect or be affected by the treatment of ibuprofen . You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines.

<u>Enhanced effect, with a possible increase in the risk of side effects:</u>

- Acetylsalicylic acid and other nonsteroidal anti-inflammatory painkillers (non-steroidal anti-inflammatory drugs), as well as glucocorticoids (medicines that contain cortisone or cortisone-like substances) can increase the risk of gastrointestinal bleeding.
- Methotrexate (medicine to treat cancer and certain types of rheumatic disease): administration of ibuprofen within 24 hours before or after dosing with methotrexate can lead to higher methotrexate concentrations and an increase in its undesirable effects.
- Anticoagulants (blood-thinners) such as warfarin.
- Digoxin (used to strengthen the heart), phenytoin (used to treat seizures) or lithium (used to treat certain psychiatric disorders); ibuprofen can increase the concentration of these medicines in the blood. A check of blood levels is not as a rule required if used as directed (over 3 or 4 days maximum).
- Antiplatelet agents and selective serotonin-reuptake inhibitors/SSRIs (medicines for treating depression) may also increase the risk of bleeding of stomach and intestines.

<u>Weakened effect:</u>

- Water tablets (diuretics) and medicines that reduce blood pressure (antihypertensive drugs): there could be a possible increased risk for the kidney.
- ACE inhibitors (agents for treating heart failure and high blood pressure). Furthermore, there is an increased risk that kidney dysfunction may occur.

- Acetylsalicylic acid in a low dose: the anti-thrombotic effect of low-dose acetylsalicylic acid may be impaired.
- Mifepristone (used for medical termination of pregnancy): if NSAIDs are used within 8 – 12 days after mifepristone administration, they can reduce the effect of mifepristone.

Other possible interactions:

- Potassium sparing diuretics: may lead to an increase in blood potassium levels.
- Probenecid and sulfinpyrazone (medicines to treat gout): may delay the excretion of ibuprofen. This can cause ibuprofen to accumulate in the body and increase its undesirable effects.
- Quinolone antibiotics: there may be an increased risk of convulsions.
- Voriconazole, fluconazole (CYP2C9 inhibitors) (used for fungal infections) can increase blood levels of ibuprofen. Reduction of the ibuprofen dose should be considered, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.
- Sulfonylureas (medicines for diabetes): NSAIDs can increase the hypoglycemic effect of sulphonylureas. Monitoring of blood sugar levels is recommended as a precaution during combined use.
- Tacrolimus: if the two medicines are administered simultaneously, kidney damage may occur.
- Cyclosporine (medicine to suppress the immune reaction): kidney damage may occur.
- Cholestyramine (used to lower cholesterol): prolonged and reduced (25%) absorption of ibuprofen. The medicines should be administered with at least two hours interval.
- Zidovudine (medicine for treating HIV/AIDS): increased risk of joint effusion and bruises in HIV-positive patients with haemophilia.
- Aminoglycoside (antibiotics): can slow down the elimination of aminoglycosides and increase their toxicity.
- Herbal extracts: Ginkgo biloba (used to treat dementia) may potentiate the risk of bleeding.

Ibuprofen can alter the results of some analytical test:
Tell your doctor if you are going to undergo clinical analysis and you are using or you have recently used ibuprofen, as it may alter the results.

Ibuprofen Farmalider with and alcohol:

Alcohol intake should be avoided during treatment with ibuprofen since it may enhance the side effects of ibuprofen, especially those affecting the stomach, intestines or brain.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, 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 a pregnancy is established during use of ibuprofen then the doctor is to be notified.

Do not take Ibuprofen Farmalider 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 Farmalider 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 Farmalider 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

The active substance ibuprofen and its breakdown products pass into breast milk only in small quantities. As negative consequences for the infant have not yet become known, an interruption of breast-feeding is not required as a rule on short-term use at the recommended dose to treat mild to moderate pain or fever.

Fertility
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
As side effects such as tiredness, dizziness and visual disturbances may occur on use of ibuprofen, the ability to react and the ability to take part actively in road traffic and to operate machines may be impaired in isolated cases. This applies to a greater extent when taken in combination with alcohol, as it potentiates these effects.

Ibuprofen Farmalider contains lactose monohydrate.

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

3. How to take Ibuprofen Farmalider

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

For short-term treatment only.
You can minimize the occurrence of adverse reactions if you use the lowest effective dose for the shortest duration necessary to control symptoms.

<u>The recommended dose is:</u>
The dosage is in line with the details in the following table.

Body weight **(Age)**	**Single dose**	**Maximum daily dose**
40 kg and above (Adults and adolescents from 12 years)	200-400 mg ibuprofen (1-2 tablets)	1200 mg ibuprofen (6 tablets)

The respective dosing interval should be chosen in line with the symptoms and the maximum daily dose. The interval between doses should not be below 6 hours. You should not exceed the maximum recommended daily dose.
If in adolescents aged from 12 years old this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

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).

If in adults this medicinal product is required for more than 3 days in the case of fever or for more than 4 days in the treatment of pain, or if symptoms worsen a doctor should be consulted.

Use in children

Ibuprofen Farmalider should not be used in adolescents under 40 kg body weight or children under 12 years of age.

Method of administration

For oral use. The tablets should be swallowed whole with a glass of water.

It is recommended that patients with a sensitive stomach take Ibuprofen Farmalider during meals.

If you take more Ibuprofen Farmalider than you should

If you have taken more Ibuprofen Farmalider than you should, or if children have been 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 can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you greatly exceed the recommended dosage, please seek medical assistance without delay. Symptoms following acute overdose with ibuprofen are usually limited to abdominal pain, nausea, vomiting and diarrhoea. Ringing in the ears, headache, dizziness, vertigo and gastrointestinal bleeding may also occur. Severe poisoning may result in light-headedness, excitation, disorientation, coma, convulsions, myoclonic cramps in children, a fall in blood pressure, respiratory depression, bluish discoloration of the skin, metabolic acidosis, increased bleeding tendency, acute kidney failure and liver damage. Worsening of asthma in asthmatics may occur.

If you forget to take Ibuprofen Farmalider

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

If you have any questions of 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.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. The following list of side effects includes all known side effects associated with ibuprofen treatment, including those experienced by patients with rheumatism undergoing high-dose, long-term therapy. The frequency data, apart from very rare reports, are based upon short-term administration of maximum daily doses of 1200 mg ibuprofen for oral dosage forms and a maximum of 1800 mg for suppositories.

Regarding the following side effects, it must be taken into account that they are mainly dose-dependent and vary from patient to patient.

The most commonly side effects concern the digestive tract. Stomach/duodenal ulcers (peptic ulcers), perforation (hole the wall of the stomach or intestine) or gastrointestinal bleeding, sometimes fatal, particularly in elderly patients may occur (see Section 2). The following have been reported after ibuprofen use nausea, vomiting, diarrhoea, flatulence, constipation, indigestion, abdominal pain, tarry stools, inflammation of the oral mucosa with ulceration (ulcerative stomatitis), exacerbation of colitis and Crohn’s disease.

Less frequently, stomach inflammation (gastritis) has been observed.

Oedema (fluid retention), high blood pressure arterial and heart failure have been reported in association with treatment of NSAID treatment

Medicines like ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

STOP TAKING this medicine and seek immediate medical help if you develop:

- signs of intestinal bleeding such as: relatively severe pain in the abdomen, black tarry stools, blood in your faeces (stool/motions), vomiting blood or dark particles that look like coffee grounds.
- signs of serious allergic reactions such as skin rashes, swelling of the face, tongue or throat, wheezing or shortness of breath, worsening of asthma, difficulty breathing, racing heart, drop in blood pressure leading to shock.
-severe skin reactions such as rashes covering the whole body; peeling, blistering or flaking skin.

Other side effects

Common (may affect up to 1 in 10 people)

- gastrointestinal complaints such as heartburn, abdominal pain, nausea (feeling sick), vomiting (being sick), flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people)

- hypersensitivity reactions with skin rash and itching, as well as asthma attacks (possibly with drop in blood pressure). A doctor is to be informed at once in this case, and ibuprofen must no longer be taken.
- central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness.
- visual disturbance. A doctor is to be informed at once in this case, and ibuprofen must no longer be taken.
- inflammation of the stomach lining (gastritis).
- gastrointestinal ulcers, in some cases with bleeding and perforation.
- ulcerative stomatitis, exacerbation of colitis and Crohn's disease.
- skin rash, urticaria, itching, purpura (including allergic purpura).

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

- sensation of sounds in the ears (tinnitus), hearing disorders.
- kidney tissue damage (papillary necrosis), particularly in long-term therapy and increased uric acid concentration in the blood.

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

- exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis). If signs of infection appear or get worse while you are using ibuprofen e.g. redness, swelling, high temperature, pain, fever), a doctor should be consulted immediately.
- signs of inflammation of the brain membranes (aseptic meningitis), such as severe headache, nausea, vomiting, fever, stiff neck or clouding of consciousness. Patients who have previously experienced certain immune system disorders (systemic lupus erythematosus and mixed connective tissue disease) appear to be at increased risk.
- blood formation disorders (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis). The first signs may be fever, sore throat, superficial wounds in the mouth, influenza-like complaints, severe fatigue, nosebleeds and skin bleeding. In these cases, stop taking the medicine immediately and go to a doctor. Do NOT attempt any kind of self-treatment with pain- or fever-lowering medicines.
- severe general hypersensitivity reactions. These may manifest as: facial oedema, swollen tongue, swollen inner larynx with airway constriction, shortness of breath, palpitations, a drop in blood pressure or even life-threatening shock.
- psychotic reactions, depression.

- reversible toxic amblyopia.
- heartbeat sensations, heart failure, heart attack.
- high blood pressure.
- inflammation of the gullet and the pancreas.
- formation of diaphragm-like strictures in the bowel.
- liver dysfunction or acute inflammation of the liver. Liver failure or damage, particularly in long-term use, shown by yellowing of the skin and eyes or pale stools and dark urine.
- hair loss (alopecia).
- photosensitivity reactions, allergic vasculitis
- severe skin reactions, such as skin rash with redness and blister formation (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome). In isolated cases, severe skin infections with soft-tissue complications may occur during varicella infections.
- lessening of urine excretion and increased build-up of tissue fluid (oedema), particularly in patients with high blood pressure or impaired kidney function; nephrotic syndrome (fluid accumulation within the body (oedema) and too much protein in the urine); inflammatory kidney disease (interstitial nephritis), which may be accompanied by acute kidney dysfunction. Reduced urine output, fluid accumulation within the body (oedema) and generally feeling unwell can be signs of kidney disease and even kidney failure.

Not known (frequency cannot be estimated from the available data):
- a severe skin reaction known as DRESS syndrom can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- 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). Stop using Ibuprofen Farmalider if you develop these symptoms and seek medical attention immediately. See also section 2. Skin becomes sensitive to light.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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

5. How to store Ibuprofen Farmalider

Keep this medicine out of the sight and reach of children.
Do not store above 25ºC.
Do not use this medicine after the expiry date which is stated on the blister or carton after EXP. The expiry date refers to the last day of the month.
Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ibuprofen Farmalider contains

- The active substance is ibuprofen. Each film-coated tablet contains 200 mg of ibuprofen.
- The other excipients are:

  Core

  Hypromellose, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate.

  Coating

  Hypromellose, titanium dioxide (E-171), talc, propylene glycol (E-1520).

What Ibuprofen Farmalider looks like and content of the pack.

Ibuprofen Farmalider is an oblong, biconvex, white-coloured coated tablets with a score line on one side and smooth on the opposite side. The dimensions of the film-coated tablets are 6 mm wide, 12 mm long and 4.2 mm thick.

The package material consists Aluminium foil / PVC / PVDC blisters.

Each pack contains 20 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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