Package leaflet: Information for the patient

Irfen 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 a doctor if you do not feel better or if you feel worse
  - after 3 days in adolescents
  - after 7 days in adults.

What is in this leaflet:

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

1. What Irfen is and what it is used for

Irfen belongs to a group of medicines called NSAID (non-steroidal anti-inflammatory drugs) which work by reducing pain, inflammation and fever.

Irfen 400 mg is used to provide relief from mild to moderate pain such as headache, including migraine headache, dental pain, period pain and fever.

2. What you need to know before you take Irfen

Do not take Irfen:
- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if you have 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 drugs for pain and inflammation (NSAIDs).
- if you have suffered from an ulcer or bleeding in the stomach or small intestine (duodenum) related to previous use of drugs for pain and inflammation (NSAIDs)
- if you are suffering from an ulcer or bleeding in the stomach or small intestine (duodenum) or if you have had two or more of these episodes in the past
- if you suffer from severe liver, kidney or heart problems (including coronary heart disease)
- if you are in the last 3 months of pregnancy

- if you are suffering from significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- if you have any active bleeding (including in the brain)
- if you suffer from a condition of unknown origin resulting in abnormal formation of blood cells

Do not give Irfen 400 mg film-coated tablets to children younger than 12 years.

Warnings and precautions
Talk to your doctor before taking Irfen
- if you have Systemic Lupus erythematosus (SLE) or other autoimmune diseases
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria)
- if you have chronic inflammatory intestinal diseases such as inflammation of the colon with ulcers (ulcerative colitis), inflammation affecting the digestive tract (Crohn's disease), or other stomach or intestinal diseases
- if you have disturbances in the formation of blood cells
- if you have problems with normal blood clotting mechanism
- if you suffer from allergies, hay fever, asthma, chronic swelling of nasal mucosa, sinuses, adenoids, or chronic obstructive disorders of the respiratory tract because the risk for developing narrowing of the airways with difficulty in breathing (bronchospasm) is greater
- if you suffer from circulation problems in the arteries of your arms or legs
- if you have liver, kidney, heart problems or high blood pressure
- if you have just had major surgery
- if you are in the first six months of pregnancy
- if you are breast-feeding
- if you have an infection – please see heading "Infections" below.

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
If you have earlier had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen, and report them at once to your doctor, especially if these symptoms occur at the beginning of treatment. This is because the risk for bleeding or ulceration of the digestive tract is higher in this case, especially in elderly patients. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.

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 also be fatal.

The risk of ulcers, perforation or bleeding in the stomach or intestines generally increases with higher doses of ibuprofen. The risk also increases if certain other medicines are taken at the same time as ibuprofen (see 'Other medicines and Irfen', below).

Skin reactions
Serious skin reactions have been reported in association with ibuprofen treatment. You should stop taking Irfen 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
Irfen may hide signs of infections such as fever and pain. It is therefore possible that Irfen 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.

Effects on the heart and brain
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 (7 days in adults or 3 days in adolescents).

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

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.

Aseptic meningitis (inflammation of the brain membrane without bacterial infection)
During treatment with ibuprofen, some cases of meningitis (presenting as stiff neck, headache, nausea, vomiting, fever or disorientation) have been seen. Although it is probably more likely to occur in patients with existing autoimmune disorders such as systemic lupus erythematosus or mixed connective tissue diseases, it has been reported in patients who do not have an existing long-term disease.

Other precautions
During long-term, high-dose use of pain killers headache may occur which should not be treated with high doses of this medicine.

The habitual use of painkillers may cause permanent damage to the kidneys and a risk of kidney failure.

Ibuprofen may temporarily prolong bleeding time.

During chicken pox (varicella) it is advisable to avoid the use of Irfen.

Irfen may decrease your chance of becoming pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Children and adolescents
Do not use in children younger than 12 years.

Ibuprofen may cause kidney problems in children and adolescents who are dehydrated.

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

The side effects of Irfen may be increased if certain medicines are taken at the same time. On the other hand, Irfen may increase or decrease the effect of other medicines or increase their side effects when taken at the same time.
Irfen may affect or be affected by some other medicines. For example:
- other NSAIDs
- medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, heparin, ticlopidine)
- platelet aggregation inhibitors (against clotting) such as clopidogrel
- methotrexate (used to treat cancer and auto-immune diseases)
- digoxin (for treatment of various heart conditions)
- phenytoin (used in prevention of the occurrence of epileptic seizures)
- lithium (used to treat depression and mania)
- diuretics (water tablets), including potassium-sparing diuretics
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- cholestyramine (used in the treatment of high cholesterol)
- aminoglycosides (medicines against certain types of bacteria)
- SSRIs (medicines against depression) such as paroxetine, sertraline, citalopram
- moclobemide (RIMA – a medicine to treat depressive illness or social phobia)
- ciclosporin, tacrolimus (for immuno-suppression after organ transplant)
- zidovudine or ritanovir (used to treat patients with HIV)
- mifepristone
- probenecid or sulfinpyrazone (for treating gout)
- quinolone antibiotics
- sulphonylureas (to treat type 2 diabetes)
- corticosteroids (used against inflammations)
- bisphosphonates (used in osteoporosis, Paget's disease and to reduce high blood calcium levels)
- oxpentifylline ((pentoxifylline) used in the treatment of circulatory disease of the arteries of the legs or arms)
- baclofen (a muscle relaxant)

Consult a doctor before taking Irfen if you use any of the above mentioned medicines.

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

Irfen with food and drink
You should swallow Irfen with a glass of water during or after a meal.

Avoid alcohol since it may enhance the side effects of Irfen, especially those affecting the stomach, intestines or brain.

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.

Ibuprofen must not be taken in the last 3 months of pregnancy since it may cause major heart, lung and kidney disorders in the unborn child. If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions thus delaying the onset of delivery.

You should only use Irfen in the first 6 months of pregnancy after consulting your doctor and only when clearly necessary.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Ibuprofen appears in breast milk in a very small amount and breastfeeding will usually not need to be stopped during short-term treatments. If, however, longer treatment is prescribed, early weaning should be considered.

Driving and using machines
Ibuprofen generally has no adverse effects on the ability to drive or operate machinery. However since at high dosage side effects such as fatigue, somnolence, vertigo (reported as common) and visual disturbances (reported as uncommon) may be experienced the ability to drive a car or operate machinery may be impaired in individual cases. This effect is potentiated by simultaneous consumption of alcohol.

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

3. How to take Irfen

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.

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).

Adults should not take Irfen for longer than 7 days without medical advice.
Adolescents should not take Irfen for longer than 3 days without medical advice.

The ibuprofen dose depends on the patient's age and body weight.
The recommended dose is:

Mild to moderate pain and fever
Adults and adolescents older than 12 years (≥40 kg):
½ to 1 tablet given as a single dose or 3-4 times a day with an interval of 4 to 6 hours.
The maximum daily dose should not exceed 3 tablets (1200 mg).

Migraine headache
Adults and adolescents older than 12 years (≥40 kg):
1 tablet given as a single dose, if necessary 1 tablet with intervals of 4 to 6 hours.
The maximum daily dose should not exceed 3 tablets (1200 mg).

Period pain
Adults and adolescents over 12 years of age:
½ to 1 tablet 1-3 times a day, with an interval of 4-6 hours, as needed. The maximum daily dose should not be more than 3 tablets (1200 mg).

The tablet should be swallowed with a glass of water during or after a meal. For the ease of swallowing or adjusting of doses the tablets can be divided in equal halves.

If you are an adult and your condition has not improved within 7 days or has worsened, you should contact a doctor. If an adolescent requires this medicine for more than 3 days, or if symptoms worsen, a doctor should be consulted.

Use in children
Irfen 400 mg film-coated tablets should not be given to children under 12 years of age.

Elderly
If you are elderly you should always consult your doctor before using Irfen since 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 kidney or liver function
If you suffer from reduced kidney or liver function, always consult your doctor before using Irfen. Your doctor will advise you accordingly.

If you take more Irfen than you should
If you have taken more Irfen than you should, or if a child has taken this medicine by accident, always contact a doctor or your 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, diarrhoea, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. Bleeding from the stomach or intestines may also occur.

At high doses and in more serious cases of overdose, drowsiness, chest pain, palpitations, loss of consciousness, excitation, disorientation, coma, convulsions (mainly in children), weakness, dizziness, cramps (especially in children), blurred vision and eye problems, kidney failure, blood in urine, liver damage, low blood pressure, cold body feeling, breathing problems, bluish discolouration of lips, tongue and fingers, and increased bleeding tendency have been reported. Worsening of asthma in asthmatics can also occur.

If you forget to take Irfen
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.

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

The side effects are stated according to the frequency they occur. The following convention has been used:
Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

The following side effects are important and will require immediate action if you experience them. You should stop taking Irfen and see your doctor immediately if the following symptoms occur:

Common:
- black tarry stools or blood-stained vomit (digestive tract ulcer with bleeding)

Very rare:
- swelling of the face, tongue or throat (larynx) which can cause great difficulty in breathing (angioedema), rapid heartbeat, severe fall in blood pressure or life threatening shock
- a sudden allergic reaction with shortness of breath, wheezing and drop of blood pressure
- severe rash with blisters on the skin especially on the legs, arms, hands and feet which can also involve the face and lips (erythema multiforme, Stevens-Johnson´s syndrome). This can get even more severe, the blisters get larger and spread out and parts of the skin may slough off (Lyell´s syndrome). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle

Not known:
- A severe skin reaction known as DRESS syndrome 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 Irfen if you develop these symptoms and seek medical attention immediately. See also section 2.

You should stop taking the medicine and contact your doctor as soon as possible if you develop the following side effects:

Very common:
- heartburn, abdominal pain, indigestion

Uncommon:
- blurred vision or other eye problems such as sensitivity to light
- hypersensitivity reactions such as skin rash, itching, asthma attacks (sometimes with low blood pressure)
- photosensitivity (increased sensitivity to sunlight)

Rare:
- vision loss

Very rare:
- sudden filling of lungs with water resulting in difficulty to breathe, high blood pressure, water retention and weight gain

Other possible side effects with /.../ are:

Very common:
- Disturbances in the digestive tract, such as diarrhoea, feeling sick, vomiting, wind, constipation

Common:
- 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 anemia
- Mouth ulcers and inflammation
- Headache, sleepiness, vertigo, dizziness, fatigue, agitation, insomnia and irritability

Uncommon:
- Inflammation of the stomach lining
- Kidney problems including development of oedema, inflammation of the kidneys and kidney failure
- Runny nose
- Difficulty breathing (bronchospasm)

Rare:
- 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:
- Unpleasant awareness of heart beat, heart failure, 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
- Acute inflammation of the liver, yellowish discolouration of the skin or whites of the eyes, liver dysfunction, damage or failure
- Damage of the kidney tissue
- Hair loss

Not known:
- Tingling of the hands and feet
- Anxiety
- Impaired hearing
- General feeling of being unwell
- Inflammation of the optic nerve which may cause vision problems
- Inflammation of the brain membrane without bacterial infection (aseptic meningitis)

Irfen 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.

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 ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Irfen

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

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

This medicinal product does not require any special storage conditions.

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 Irfen contains

- The active substance is ibuprofen. Each film-coated tablet contains 400 mg ibuprofen.
- The other ingredients are:
  Tablet core: cellulose, microcrystalline, silica, colloidal anhydrous, hydroxypropylcellulose, sodium laurylsulfate, croscarmellose sodium, talc
  Film coating (Opadry (white) 06B28499): hypromellose, macrogol 400, titanium dioxide (E171).

What Irfen looks like and contents of the pack

Film-coated tablet.
400 mg: White, oval, biconvex film-coated tablets with a score on one face.

Pack sizes:

Blisters:
6, 10, 12, 20, 24, 30, 36, 50 and 100 film-coated tablets.

Tablet container:
10, 20, 30 and 50 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Buplex 400 mg film coated tablets
Malta	Irfen 400 mg
Norway	Ifenin
Poland	IbuTeva Max
Romania	Adagin 400 mg comprimate filmate
Sweden	Ifenin

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