

Package leaflet: Information for the user  
Ibuprofen 400mg film-coated Tablets

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

**1. What Ibuprofen is what it is used for**

Ibuprofen 400mg film-coated tablets contains the active substance ibuprofen and is referred to as Ibuprofen throughout this leaflet. Ibuprofen belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Ibuprofen reduces fever, relieves pain and has an anti-inflammatory effect.

For adults and adolescents from 12 years of age (weighing 40 kg or more), this medicine is used for: Symptomatic treatment of pain and inflammation in arthritic diseases (e. g. rheumatoid arthritis), degenerative arthritic conditions (e. g. osteoarthritis), and in painful swelling and inflammation after soft tissue injuries.

Symptomatic treatment of mild to moderate pain and/or fever.

This medicine should only be used in adults and adolescents over 12 years and weighing over 40 kg in bodyweight.

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

**Do not take Ibuprofen if:**

- you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have stomach ulcer or duodenal ulcer or have had recurrent ulcer or bleeding in the stomach or intestine
- if you have severe liver or kidney disease
- if you have severe heart failure
- if you have a condition that causes an increased tendency to bleed
- if you have bleeding in the brain (cerebrovascular bleeding) or other active bleeding
- if you previously have had bleeding or perforation in your stomach or intestine when treated with ibuprofen or a similar product (other NSAIDs).
- if you are in the last three months of pregnancy
- if you have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction,

- rash) to acetylsalicylic acid or other anti-inflammatory drugs (NSAIDs).
- if you have unclarified blood-formation disturbances
  - if you are severely dehydrated (e.g. caused by vomiting, diarrhoea or insufficient fluid intake)

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Ibuprofen:

- if you have asthma, chronic rhinitis (chronic stuffy and runny nose) or allergic diseases since this medicine can cause difficulty breathing, hives or a serious allergic reaction when you have any of these conditions.
- if you have certain disorders of the immune system (mixed connective tissue disorders and systemic lupus erythematosus (SLE), conditions of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs) as there may be an increased risk of aseptic meningitis
- if you have impaired kidney or liver function
- 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 of feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- if you have inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed.
- if you are dehydrated, as there is a risk of renal impairment, especially in dehydrated adolescents and the elderly.
- if you have an infection - please see heading “Infections” below.

Talk to your doctor or pharmacist before taking this medicine if any of the above applies to you.

#### Lowest effective dose

Always aim for the lowest possible dose and shortest possible treatment time to reduce the risk of side effects. It is generally the case that higher than recommended doses can entail risks. This also means that the combination of several NSAID products at the same administration time should be avoided.

If you use painkillers for a long time, this can cause headaches, which should not be treated with more painkillers. If you think this applies to you, talk to your doctor or pharmacist

#### Heart attack and stroke

Anti-inflammatory/pain-killer medicines like this medicine 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.

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

#### Gastrointestinal bleeding, ulceration or perforation

Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms (especially gastrointestinal

bleeding), particularly at the start of treatment.

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

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

#### Infections

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

During chicken pox it is advisable to avoid use of this medicine.

#### Elderly

Elderly patients should be aware of their increased risk of adverse events, especially bleeding and perforation in the digestive tract, which may be fatal.

#### Children and adolescents

There is a risk of renal impairment especially in dehydrated adolescents. This medicine is not suitable for use in adolescents and children under 12 years of age and is not suitable for adolescents weighing under 40 kg bodyweight.

### **Other medicines and Ibuprofen**

Do not use different types of pain-relieving medicines at the same time unless directed by a doctor.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This medicine may affect or be affected by some other medicines.

For example:

- methotrexate (medicine for tumours and immune system disorders)
- lithium (medicine for manic depressive illness)
- digoxin (medicine for irregular heart beat)
- phenytoin ( medicine for epilepsy)
- acetylsalicylic acid (for pain)
- medicines that are ant-coagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan)
- medicines called SSRIs - selective serotonin reuptake inhibitors (for depression)
- medicines that suppress your immune system, such as ciclosporine or tacrolimus (rejection in patients receiving organ transplants)
- corticosteroids (medicines for inflammation)
- some antibiotics including aminoglycosides and quinolone antibiotics (for treating bacterial

infections)

- antifungals particularly voriconazole or fluconazole (for treating fungal infections)
- sulphonylureas (for diabetes mellitus)
- cholestyramine (medicine for high cholesterol)
- zidovudine (for treating human immunodeficiency virus (HIV) infection)
- mifepristone (for pregnancy termination)
- diuretics (water tablets)

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

### **Ibuprofen with alcohol**

If you drink alcohol while taking this medicine, you may be more likely to get side effects.

### **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**

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 during 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 take longer than expected.

You should not take this medicine 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, this medicine 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**

This medicine passes into breast milk but is unlikely to affect the breastfed child. Consult a doctor if you need to use this medicine for more than occasional use during breastfeeding.

#### **Fertility**

This medicine may make it more difficult to become pregnant. The use of this medicine is not recommended while attempting to conceive or during investigation of infertility. You should inform your doctor if you are planning to become pregnant or if you have problems getting pregnant.

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

This medicine may impair reactions in some people, for example due to side effects such as visual disturbance, dizziness or drowsiness. This should be taken into consideration on occasions when high alertness is required, e.g. driving, and applied to a greater extent in combination with alcohol.

#### **Ibuprofen 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 medicine.

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

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

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 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

The recommended dose is:

#### **For pain and/or fever**

Take one 400 mg tablet as a single dose. Additional doses of 400 mg ibuprofen can be taken if needed. The interval between doses depends on the symptoms and the recommended maximum daily dose. The interval should not be less than 6 hours. Do not take more than 1200 mg of ibuprofen within 24 hours.

#### **For rheumatic diseases and painful swelling and inflammation following soft tissue injuries**

##### Adults:

The usual single dose is 400-800 mg of ibuprofen. The recommended daily dose is 1200-1800 mg in divided doses. There should be an interval of at least 6 hours between doses. For some patients, a maintenance dose of 600-1200 mg per day may be sufficient. In severe or acute conditions, it may be beneficial to increase the dose until the acute phase is under control, provided that the total daily dose divided into several doses does not exceed 2400 mg.

##### Adolescents from 12 years (weighing 40 kg or more):

The recommended dose should be adjusted according to body weight: 20-40 mg/kg daily (maximum 2400 mg per day) divided into 3-4 single doses.

#### **Method of Administration**

Ibuprofen 400mg film-coated tablets is for oral use.

Take the tablets with a glass of water.

The tablets should not be crushed, chewed or sucked to avoid oral discomfort or throat irritation.

#### **Duration of treatment**

The treating physician decides on the duration of treatment.

In rheumatic diseases the use of Ibuprofen 400mg film-coated tablets can be required for a longer period.

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

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

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

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

If you forget to take this medicine, take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all.

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.

If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

#### **Serious side effects**

**Stop taking Ibuprofen and contact a doctor immediately if you develop any of the following:**

- Angioedema (an uncommon side effect) with symptoms such as:
  - swelling of the face, tongue or throat,
  - difficulties swallowing,
  - hives and difficulties breathing.
- 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. This medicine may cause a reduction in the number of white blood cells (agranulocytosis) with decreased resistance to infection (an uncommon side effect). It is important to inform your doctor about your 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].
- 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).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome Frequency not known (frequency cannot be estimated from the available data).

#### **Other side effects that may occur:**

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

- Headache, lightheadedness
- Gastrointestinal side effects (indigestion, diarrhoea, nausea, vomiting, abdominal pain, flatulence, constipation, black stools, bleeding in stomach and intestine, vomiting blood)
- Rash
- Tiredness

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

- Rhinitis
- Hypersensitivity
- Insomnia, anxiety
- Visual disturbances, hearing impairment
- Bronchial spasm, asthma
- Mouth ulceration
- Stomach ulcer, intestinal ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach
- Hepatitis, jaundice, abnormal liver function

- Itching, small bruises in skin and mucous membranes
- Photosensitivity
- Impaired kidney function
- Changes in blood count
- Anaemia (a reduction in red blood cells or hemoglobin, which can make the skin pale and may lead to weakness)
- Drowsiness
- Tingling sensation
- Hearing loss

**Rare (may affect up to 1 in 1000 people):**

- Non-bacterial meningitis
- Allergic reaction
- Depression, confusion
- Impaired vision, tinnitus (ringing in ears), dizziness
- Liver damage and fluid retention in body

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

- Inflammation of the pancreas, liver failure

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

- Worsening of ulcers in the large intestine (colitis) and Crohn's Disease (bowel disease)
- Heart failure, heart attack, high blood pressure

Please note that this medicine can prolong bleeding time.

Exceptionally, serious infections of the skin in case of chicken pox. When an NSAID is used, an infection-related inflammation of the skin could develop or become more severe (e.g. a condition such as necrotising fasciitis may develop characterized by intense pain, high fever, swollen and hot skin, blistering, necrosis). If signs of an infection of the skin occur or get worse during use of this medicine you are recommended to see your doctor immediately.

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

**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 directly via the 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**

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 carton after EXP. 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 contains:**

The active substance is ibuprofen.  
Each film-coated tablet contains 400mg ibuprofen.

The other ingredients are:

Tablet core: Colloidal anhydrous silica, Microcrystalline cellulose, Lactose monohydrate (see Section 2), Croscarmellose sodium, Sodium laurilsulfate, Magnesium stearate.

Tablet coating: Hypromellose, Talc

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

Ibuprofen 400mg film-coated tablets are white or off-white, capsule-shaped film-coated tablets, marked I4 on one side. The tablets are approximately 17mm long and 8mm wide. They are available in packs of 12, 14, 15, 16, 20, 24, 28, 30, 48, 50, 56, 60, 84, 90, 100, 112, 250, and 500 film-coated tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

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**Manufacturer:**

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