

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Ibuprofen 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.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 tablets is and what it is used for
2. What you need to know before you take Ibuprofen tablets
3. How to take Ibuprofen tablets
4. Possible side effects
5. How to store Ibuprofen tablets
6. Contents of the pack and other information

#### **1. What Ibuprofen tablets is and what it is used for**

Ibuprofen tablets belong to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Ibuprofen tablets reduces fever, relieves pain and has an anti-inflammatory effect.

In adults and children over 12 years (>40 kg): Short term treatment of fever and pain of mild to moderate intensity, including dysmenorrhea.

Long term symptomatic treatment of pain and inflammation in chronic inflammatory rheumatic diseases.

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

##### **Do not take Ibuprofen tablets:**

- if you are allergic (hypersensitive) to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if you are in the last three months of pregnancy.
- if you have an increased tendency to bleed.
- if you have severe liver and kidney disease.
- if you have severe heart failure or coronary heart disease.
- if you have a stomach ulcer, duodenal ulcer, or if you have had a stomach ulcer or duodenal ulcer previously when treated with ibuprofen or a similar product.
- if you have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction, rash) to acetylsalicylic acid or other anti-inflammatory drugs.
- If you are suffering from bleeding on the brain (cerebrovascular bleeding) or other active bleeding.
- if you are suffering from significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).

##### **Warnings and 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 tablets 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").
  - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
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- 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.
  - People who have or have had the following illnesses or symptoms should consult a doctor before starting treatment with Ibuprofen tablets: systemic lupus erythematosus (connective tissue disease), impaired kidney or liver function, mild to moderate heart failure, asthma, inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed.
  - Like other anti-inflammatory drugs, Ibuprofen tablets can mask signs of infection.
  - This product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.
  - Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms, particularly at the start of treatment.
  - Serious skin reactions have been reported in very rare cases when using a NSAID. Patients seem to be at highest risk early in the course of therapy, the onset of the reaction occurring in the majority of cases in the first month of treatment. Stop taking Ibuprofen tablets and contact a doctor if you develop a rash or mucous membrane lesions.
  - In patients with Systemic lupus erythematosus and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.
  - Stop taking Ibuprofen tablets and contact a doctor immediately if you develop any of the following symptoms (angioedema)
    - swelling of the face, tongue or throat,
    - difficulties swallowing,
    - hives and difficulties breathing.
  - Medicines like Ibuprofen tablets may entail a slightly increased risk of heart attack or stroke. This increased risk is more likely when using high doses and in long-term treatment. Do not exceed the recommended dose or treatment time.
  - Consult a doctor or pharmacist about your treatment if you have heart problems, if you previously have had a stroke or if you think that you have an increased risk for these conditions (for example, if you have high blood pressure, diabetes, high cholesterol levels or if you smoke).
  - Do not take Ibuprofen tablets if you are planning a pregnancy. Consult your doctor first.

- During varicella it is advisable to avoid use of this drug.
- Serious skin reactions have been reported in very rare cases when using a NSAID. Stop taking Ibuprofen tablets and contact a doctor if you develop a rash or mucous membrane lesions. The severe rashes may include 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, where the blisters get larger and spread out and parts of the skin may slough off (toxic epidermal necrolysis). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle.
- Ibuprofen tablets 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.
- If you have been told by your doctor that you have intolerance to some sugars.

### **Children and adolescents**

There is a risk of renal impairment in dehydrated children and adolescents.

### **Other medicines and Ibuprofen tablets:**

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 or have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

- tumours and immune system disorders (methotrexate, tacrolimus, ciclosporin, pemetrexed),
- manic depressive illness (lithium),
- irregular heart beat (digoxin),
- pain (acetylsalicylic acid),
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine, dicumarol),
- depression (medicines called SSRIs),
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- inflammation (corticosteroids).
- fungal infections (antifungals particularly voriconazole or fluconazole)
- diabetes mellitus (sulphonylureas)
- human immunodeficiency virus (HIV) infection (zidovudine, ritonavir)
- antibiotic (quinolones such as ciprofloxacin)
- aminoglycosides (a type of antibiotic)
- mifepristone
- probenecid
- any other ibuprofen preparations, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including acetylsalicylic acid
- cholestyramine (a drug used to lower cholesterol)
- Gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

For this reason, the doctor treating you needs to know about all the medicines you are taking.

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

#### **Ibuprofen tablets with food and drink**

Ibuprofen tablets could be used together with food and drinks.

#### **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*

Pregnant women should not use Ibuprofen tablets during the three final months of the pregnancy. Use of Ibuprofen tablets should be avoided by women who are planning a pregnancy or are pregnant. Treatment at any time in pregnancy should only take place as directed by a doctor.

##### *Breast-feeding*

Ibuprofen tablets passes into breast milk. The use of Ibuprofen tablets is therefore not recommended while breast-feeding. However, consult a doctor if using Ibuprofen tablets more than occasionally while breast-feeding is required.

##### *Fertility*

The use of Ibuprofen tablets may affect fertility. The use of Ibuprofen tablets is not recommended while attempting to conceive or during investigation of infertility.

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

Ibuprofen tablets may impair reactions in some people. This should be taken into consideration on occasions when high alertness is required. Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

You alone are responsible to decide if you are in fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines. Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

#### **Ibuprofen tablets contains lactose monohydrate**

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

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

Always take Ibuprofen tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take your ibuprofen tablets with or after food, with plenty of fluid. Ibuprofen tablets should be swallowed whole and not chewed, broken, crushed or sucked on to avoid oral discomfort and throat irritation

##### *Rheumatic diseases*

- initial treatment: 2x400 mg tablets, three times daily, i.e. 2400 mg per day
- maintenance treatment : 1x400 mg tablets, three to four times daily, i.e. 1200 to 1600 mg per day.

An interval of at least 4-6 hours should be allowed between doses. The total daily dose must not exceed 2400mg in divided doses. Some patients can be maintained on 600 – 1200mg daily.

### *Juvenile Rheumatoid Arthritis*

For Juvenile Rheumatoid Arthritis, the recommended dose is 20mg-30mg/kg body weight daily in 3 to 4 divided doses up to a maximum of 40mg/kg body weight daily in severe cases. In children weighing less than 40 kg, use of a different strength or a liquid formulation of ibuprofen should be considered to aid accurate dosing.

### *Short term symptomatic treatment of fever and pain of mild to moderate intensity:*

Adults and adolescents over 12 years (>40 kg)

One 400 mg tablet one to four times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Single doses exceeding 400 mg have not been shown to have any additional analgesic effect. The 400 mg tablet should only be used for more intense pain or fever that are not relieved by a 200 mg ibuprofen tablet.

### *Dysmenorrhoea*

One 400 mg tablet one to three times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Treatment is started at the first sign of menstruation problems.

If you have severe liver and kidney disease or are elderly your doctor will tell you the correct dose to take which will be the lowest dose possible.

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

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

The symptoms 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 forget to take Ibuprofen tablets**

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

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

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

- signs of angioedema such as
  - swelling of the face, tongue or throat,
  - difficulties swallowing,
  - hives and difficulties breathing.
- signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- signs of intestinal bleeding such as
  - passing blood in your faeces (stools/motions),
  - passing black tarry stools,
  - vomiting any blood or dark particles that look like coffee grounds.

### **Tell your doctor and stop taking Ibuprofen tablets if you experience:**

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.

- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Yellowing of the eyes and/or skin (jaundice).
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems).

Severe spreading skin rash (Stevens-Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness).

Medicines such as Ibuprofen tablets have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Medicines such as Ibuprofen tablets have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen.

Very rarely Ibuprofen tablets may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Ibuprofen tablets has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

### ***Other side effects***

*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, insomnia, anxiety.
- Visual disturbances, hearing impairment.
- Difficulty breathing, bronchial spasm, asthma.
- Mouth ulceration. Stomach ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach.
- Hepatitis. Jaundice. Abnormal liver function.
- Hives, itching, small bruises in skin and mucous membranes.
- Photosensitivity.
- Impaired kidney function.
- Drowsiness.
- Tingling sensation.
- Hearing loss.
- Anaemia (a reduction in red blood cells or hemoglobin, which can make the skin pale and may lead to weakness).

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

- Non-bacterial meningitis.
- Allergic reaction.
- Depression, confusion.
- Impaired vision, dizziness
- Liver damage and fluid retention in body.
- Changes in blood count including agranulocytosis.

- Tinnitus (ringing in ears) and vertigo.

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

- Inflammation of the pancreas, liver failure.
- Skin and mucous membrane changes (sometimes severe) such as epidermal necrolysis and/or erythema multiforme.

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

- Exacerbation of Colitis and Crohn's Disease.
- Cardiac failure.
- Myocardial infarction.
- Hypertension.
- 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).

Please note that Ibuprofen tablets can prolong bleeding time.

There have been reports of high blood pressure and heart failure as well as worsening of ulcers in the large intestine and Crohn's disease (inflammatory bowel disease) in treatment with pain-relieving medicines (NSAIDs).

Exceptional serious infections of the skin in case of varicella. Exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of NSAIDs has been described.

Medicines like Ibuprofen tablets may entail a slightly increased risk of heart attack or stroke.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

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

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

This medicinal product does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What Ibuprofen tablets contains**

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

The other ingredients are:

*Tablet core:*

Lactose monohydrate, maize starch, croscarmellose sodium, colloidal anhydrous silica, microcrystalline cellulose, magnesium stearate.

*Tablet coating:*

Hypromellose, triacetin, titanium dioxide (E171), erythrosine aluminum lake (E127).

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

Ibuprofen 400 mg film-coated tablets are pink coloured, round, approximately 13 mm in diameter, biconvex film coated tablets debossed with 'DK' on one side and plain on other side.

Ibuprofen 400 mg tablets are packaged in PVC - Aluminium blisters or PVC/PVdC – Aluminium Blisters.

Pack sizes: 10, 12, 14, 20, 21, 24, 28, 30, 40, 42, 48, 50, 60, 84, 100 or 500 film-coated tablets in carton.

Not all pack sizes may be marketed.

### **Marketing Authorisation holder:**

Accord Healthcare Limited,  
Sage House, 319 Pinner Road,  
North Harrow, Middlesex HA1 4HF,  
United Kingdom.

### **Manufacturer:**

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

<b>Member States</b>	<b>Proposed (Invented) Names</b>
United Kingdom	Ibuprofen 200/400/600 mg Film-coated Tablets
Austria	Ibuprofen Accord 400/600 mg Filmtabletten
Bulgaria	Ибупрофен Акорд 200/400/600 мг филмирани таблетки
Estonia	Ibuprofen Accord
Finland	Ibuprofen Accord 400/600 mg tabletti, kalvopäällysteinen
Ireland	Ibuprofen 200/400/600 mg Film-coated Tablets
Italy	Ibuprofene Accord
Malta	Ibuprofen 200/400/600 mg Film-coated Tablets
Netherlands	Ibuprofen Accord 200/400/600 mg Filmomhulde tabletten
Sweden	Ibuprofen Accord 200/400 mg filmdragerade tabletter
France	Ibuprofene Accord 200/400 mg, comprimés pelliculés

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