

Artwrok for Submission (Original) Purpose - UK Market



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.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years and after 10 days for adults.
- 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.

This medicine is available without prescription. However, you still need to take it carefully to get the best results from it.

- Always use 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.

What is in this leaflet

1. What Ibuprofen Tablets are 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 are and what it is used for

The name of your medicine is Ibuprofen 400 mg film-coated tablets. Ibuprofen tablets contain the active ingredient "ibuprofen", which belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs such as ibuprofen provide relief by changing the body's response to pain, swelling, and high temperature. This medicine is used in adults and adolescents weighing from 40 kg (12 years of age and above) for the symptomatic treatment of:

- Headaches and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold and flu

2 What you need to know before you take Ibuprofen Tablets

Do not take Ibuprofen Tablets if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- have or ever had a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- have had a gastrointestinal bleeding or perforation, related to previous use of NSAIDs
- are taking other NSAIDs
- are taking more than 75 mg of aspirin a day. If you are on low-dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take this medicine
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last 3 months of pregnancy
- are under 12 years old

Warnings and precautions

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 ibuprofen. Stop immediately ibuprofen and contact immediately your doctor or medical emergencies if you notice any of these signs.

Talk to your pharmacist or doctor before taking Ibuprofen Tablet if you:

- have or have had asthma
- have an infection – please see heading "infections" below
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy.
- If you are taking ibuprofen tablets for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Infections

Ibuprofen 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.

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

Taking other medicines:

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. Aspirin)

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

- medicines that are anticoagulants (i.e. thin blood / prevent clotting e.g. aspirin / acetylsalicylic acid, warfarin ticlopidine)
- medicines that reduce high blood pressure (ACE inhibitors-II such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines to help you pass water (diuretics)
- medicines for pregnancy termination (e.g. mifepristone)
- corticosteroids (e.g. prednisolone); selective serotonin reuptake inhibitors (SSRIs); cardiac glycoside (e.g. digoxin); lithium; methotrexate, ciclosporin, tacrolimus; zidovudine or quinolone antibiotics (e.g. norfloxacin).

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.

Other warnings

- This medicine belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that this medicine used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as this medicine may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, or high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.
- There is a risk of kidney problems in dehydrated children and adolescents.

Pregnancy and breast feeding

Do not take Ibuprofen if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Ibuprofen during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Ibuprofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. Speak to your doctor or pharmacist before taking this medicine if you are breastfeeding.

Driving and using machines

If you have side effects like feeling dizzy, drowsy, tired, or if you have a blurred vision after taking Ibuprofen, you should avoid driving or using any dangerous machines (see section 4 Possible side effects).

Ibuprofen tablets contains lactose

This medicinal product contains a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. essentially 'sodium free'.

3 How to take Ibuprofen Tablets

Adults and children aged 12 years and older:

This product is intended for short term use only. You should only take the lowest dose for the shortest time necessary to relieve your symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Take 1 tablet with water, up to three times a day. Leave at least four hours between doses. Do not take more than 3 tablets in 24 hours.

Do not give to children under 12 years.

In children and adolescents between 12 and 18 years

If this medicine is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

In adults

If this medicine is required for longer than 10 days or if the symptoms persist or worsen, consult your doctor.

The tablet cannot be divided into equal doses.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

If you take more Ibuprofen tablets than you should

If you have taken more tablets than you should, or if children

180 x 420 mm

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Ibuprofen 400 mg Tablets - SPUK - PONDY - Submission

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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), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also occur agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. 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. Further, the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may furthermore be low blood pressure and reduced breathing.

If you forget to take Ibuprofen Tablets

Do not take a double dose to make up for a tablet you have forgotten to take. Take the next tablet as usual.

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

4 Possible side effects

Like all medicines, Ibuprofen tablets can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Ibuprofen tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below). If you do, or if you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

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

- Signs of intestinal bleeding such as: bright red faeces (stools/ motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- Signs of serious allergic reaction such as difficulties in breathing and unexplained wheezing, dizziness or faster heartbeat, severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Stevens-Johnson syndrome), swelling of your face, tongue or throat, drop in blood pressure leading to shock
- Signs of kidney problems such as: passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)
- Signs of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or loss of consciousness. Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include widespread skin rash, high body temperature, enlarged of lymph nodes and an increase of eosinophils (a type of white blood cells).
- 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].
- 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).

STOP taking this medicine and tell your doctor if you experience the following uncommon side effects, which affect 1 to 10 users in 1,000

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed:

Uncommon side effects which affect 1 to 10 users in 1,000

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches

Rare side effects which affect 1 to 10 users in 10,000

- flatulence (wind), diarrhoea, constipation and vomiting

Very rare side effects which affect less than 1 user in 10,000

- blood disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach

(gastritis)

- liver problems

Side effects for which the frequency cannot be estimated from available data:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease

Any anti-inflammatory / pain-killer medicines such as this medicine may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking this medicine 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, have a family history of heart disease or stroke, or if you are a smoker.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please stop taking the product immediately and tell your doctor or pharmacist.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 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.
- The other ingredients are:

Tablet core: Colloidal silicon dioxide, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, magnesium stearate

Film-coating: Hypromellose, Titanium Dioxide, Lactose Monohydrate, Macrogol 4000, Sodium Citrate

What ibuprofen tablets looks like and contents of the pack

White coloured round shaped biconvex film-coated tablet debossed '4' on one side and break line on other side.

Dimension of the tablet in diameter- 12.80 mm±0.20 mm

The packs are available in PVC-Aluminium blister packs.

PVC-Aluminium Blister containing 12, 16, 24, 48, 84, 96 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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United Kingdom

This leaflet was last revised in 09/2024



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