

PACKAGE LEAFLET: INFORMATION FOR THE USER
IBUPROFEN 400mg FILM COATED TABLETS

Ibuprofen

(Referred to as Ibuprofen tablets in the remainder of the leaflet)

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 Tablet 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 TABLET IS AND WHAT IT IS USED FOR

These tablets contain the active ingredient, ibuprofen. Ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs).

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

These medicines are pain killers, reduce inflammation and high temperature.

Ibuprofen 400mg Tablets are used for:

- Rheumatic or muscular pain
- Pain of non-serious arthritic conditions (characterized by pain and stiffness in your body)
- Neuralgia (painful disorder of the nerves)
- Headache including migraine
- Toothache
- Period pain
- Feverishness
- Symptoms of cold & influenza

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IBUPROFEN TABLETS

Do not take Ibuprofen Tablets:

- If you are allergic (hypersensitive) or have had an allergic reaction to, Ibuprofen any other NSAID, aspirin, or any of the other ingredients of this medicine (listed in section 6). Symptoms of an allergic reaction may include swollen eyelids, lips, tongue, or throat
- If you have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking Ibuprofen, aspirin or similar medicines
- If you have swelling of the hands, arms, feet, ankles, or lower legs
- If you develop hives (red and sometimes itchy bumps) on your skin after taking this medicine, Aspirin or any other NSAIDs
- If you suffer from severe liver, kidney or heart problems
- If you currently have an active ulcer or a history of recurrent peptic ulcers (more than two) in your stomach or duodenum
- If you have ever had gastrointestinal bleeding or perforation when previously taking NSAIDs
- If you are in the last three months of pregnancy (see also Section 2 "Pregnancy, breast-feeding and fertility")
- If you are under 12 years old

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen Tablets:

- If you have a previous history of bronchial asthma or allergic disorders
- If you are elderly, as you may be more prone to side effects (see section 4. Possible Side Effects) which in some cases may be extremely serious or even life threatening
- If you have or have had high blood pressure
- If you have or ever had Crohn's disease (inflammation of the digestive system) or ulcerative colitis (disease that causes ulcers in the lining of the rectum and colon)

- If you have or ever had Systemic Lupus Erythematosus (SLE) a condition of the immune system resulting in joint pains, skin rashes, kidney or liver problems
- If you have kidney, heart, liver or bowel problems
- If you have high cholesterol or previously have had a heart attack or stroke
- If you are in the first 6 months of pregnancy
- If you are a smoker
- If you are taking other NSAID painkillers including a specific type called COX-2 inhibitors, or aspirin, with a daily dose above 75mg
- If you are on low-dose aspirin (up to 75mg)
- If you have an infection - please see heading "Infections" below.

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 tablets and contact immediately your doctor or medical emergencies if you notice any of these signs

Skin reactions

Serious skin reactions have been reported including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) in association with Ibuprofen tablets treatment. You should stop taking Ibuprofen tablets 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

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

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).

Other special warnings

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 (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

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

Other medicines and Ibuprofen Tablets

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

Do not use this medicine if you are:

- taking other NSAID containing products (e.g. aspirin, ibuprofen). If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine
- taking other NSAID painkillers including a specific type called COX-2 inhibitors

Ibuprofen 400mg Tablets may affect or be affected by some other medicines. Talk to your doctor or pharmacist if you are taking:

- Aminoglycosides (a type of antibiotics)
- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines used to treat depression, such as selective serotonin re-uptake inhibitors (SSRIs) and lithium
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- To help you passing water (diuretics)
- To stimulate your heart (glycosides e.g. digoxin)
- Cholestyramine (a drug used to lower cholesterol)
- Medicines used to treat cancer, such as methotrexate and mifamurtide
- Ciclosporin to dampen down the body's immune reactions
- Mifepristone used to induce abortion in first two months of pregnancy
- Medicines used to treat various illnesses that involve inflammation in the body (corticosteroids)
- Ciprofloxacin - antibiotics called Quinolones
- Tacrolimus to prevent rejection of liver transplants, for the temporary suppression of your immune system
- Phenytoin to treat epilepsy
- Antibiotics called quinolones such as ciprofloxacin
- Zidovudine to treat human immunodeficiency virus (HIV) infection
- Medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- Voriconazole or fluconazole (type of anti-fungal drugs)
- Gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

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.

Do not take Ibuprofen tablets 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 tablets 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 tablets 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. Ibuprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant. Ask your doctor or pharmacist for advice before taking any medicine. It is possible that this medicine can pass into breast milk. If you are breastfeeding, speak to your doctor or pharmacist for advice before taking this, or any medicine.

Driving and using machines

This medicine may make you feel dizzy, drowsy or tired. You may also experience blurry vision. Do not drive or use tools or machines if you are affected in any way after taking this medicine.

3. HOW TO TAKE IBUPROFEN TABLET

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with water during or after meals.

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).

The usual dose is:

Adults, the elderly and children over 12 years:

The starting dose is 1 tablet 3 times a day, as required. Leave at least four hours between doses and do not take more than three tablets in any 24 hour period. The risk of side effects is greater in the elderly, so your doctor will give you the lowest dose possible, and take special care of you.

In adults: Do not take for longer than 10 days unless your doctor tells you to. If symptoms persist or the pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

If in children: In children and adolescents between 12 and 18 years: If in children aged from 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen, a doctor should be consulted. Do not give to children under 12 years of age.

Ibuprofen Tablets are for **short term use only**. Take the lowest dose for the shortest time necessary to relieve your symptoms. Do not take Ibuprofen for longer than 10 days.

Ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you take more Ibuprofen Tablets than you should

If you or someone you know accidentally takes a lot more than the stated dose than you should contact your doctor go to your nearest hospital casualty department immediately Take this leaflet and any unused tablets with you to show the doctor.

The symptoms of an overdose include vomiting (being sick – may be blood streaked), headache, confusion, shaky eye movement, nausea (feeling sick), stomach pain and possibly diarrhoea. Dizziness, ringing in the ears (tinnitus) and fainting can also be signs of an overdose. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take Ibuprofen Tablets

If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten tablet.

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.

(Drug reaction with eosinophilia and systemic symptoms):

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.) Chest pain, which can be sign of a potentially serious allergic reaction called Kounis syndrome

Severe cutaneous adverse reactions (SCARs)

STOP TAKING Ibuprofen Tablets and seek immediate medical help if you experience:• 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.

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).

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.
- Liver, kidney problems or difficulty urinating

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.

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

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 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.

Other side effects

Common (may affect up to 1 in 10 people)

- Stomach pain, or indigestion, diarrhoea, feeling sick, being sick, wind, constipation,
- passing black tarry stools
- passing blood in your faeces (stools/motions)
- vomiting any blood
- feeling dizzy or tired
- Rash
- Headache – if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this

Uncommon (may affect up to 1 in 100 people)

- Stomach or gut ulcer, hole in the wall of the digestive tract
- Inflammation of your stomach lining, pain in your stomach (abdomen)
- Mouth ulcers
- Sneezing, blocked, itchy or runny nose (rhinitis)
- Feeling drowsy
- Feeling anxious
- Difficulty sleeping, feeling drowsy,
- Feeling a tingling sensation or 'pins and needles'
- Visual disturbances, hearing problems
- Ringing in the ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- Difficulty breathing, wheezing or coughing, asthma or worsening of asthma
- Inflammation of kidney tissue, kidney disorder causing them to leak large amounts of protein from the blood into the urine, kidney failure, appearance of blood in the urine, passing more or less urine, pain in the back and/or swelling (particularly in legs)
- Swelling of the liver that makes it stop working well (hepatitis), liver problems, nervousness, hallucinations, inflammation of eye nerve, light-headedness (loss of balance), excessive tiredness
- Serious allergic reaction which causes swelling of the face or throat
- hives, itching

Rare side effects (may affect up to 1 in 1000 people)

- A brain infection called 'non-bacterial meningitis' with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation especially in patients with diseases like lupus erythematosus (a condition in which immune system attacks healthy cells and tissues of many parts of the body), mixed connective tissue disease (overlap disease)
- Blood disorder resulting in unexplained or unusual bruising, or bleeding, fever, severe sore throat with high fever (agranulocytosis), mouth ulcers, flu like symptoms, and severe exhaustion, Low platelet count, Effectuated blood cell counts, Failure of the bone marrow to produce sufficient blood cells for the circulation (Aplastic anaemia, Abnormal breakdown of red blood cells
- Feeling depressed or confused
- Loss of vision
- Fluid retention (oedema)
- Serious allergic reaction which causes difficulty in breathing or dizziness

Very rare side effects (may affect up to 1 in 10000 people)

- Inflammation of the pancreas
- Heart failure
- Heart attack,
- High blood pressure
- Liver failure
- Skin problems (which can also affect inside your mouth, nose or ears) such as 'Stevens – Johnson syndrome', 'toxic epidermal necrolysis' or 'erythema multiforme.'

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

- Worsening of ulcerative colitis and Crohn's disease (inflammation of the colon)
- Skin becomes sensitive to light
- 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 tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

skin becomes sensitive to light

- Decreased Appetite

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 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. Do not store the tablets above 25°C. Keep them in the original pack. 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 contain:

The active substance is Ibuprofen. The other ingredients are Pregelatinised Starch, Maize Starch, Aerosil, Colloidal Anhydrous Silica, Magnesium Stearate, Hypromellose, Macrogol 6000, Erythrosine Lake (E127), Titanium Dioxide (E171) and Diocetyl Sodium Sulphosuccinate.

What Ibuprofen Tablets look like and contents of the pack:

Ibuprofen 400mg Tablets are pink, biconvex, film-coated tablets with "I 400" on one side and "LPC" on the other and packed in tablet containers of 21, 100, 250, 500, 1000 and blister packs of 12, 21, 24, 28, 48, 56, 84, 96, 100.

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