

Package leaflet: information for the user

Ibuprofen 400 mg Soft Capsules

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 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.
- Adults: You must talk to a doctor if you do not feel better or if you feel worse after 4 days for pain or 3 days for fever and migraine headaches.
- Adolescents (12 – 18 years old): You must talk to a doctor if the adolescent does not feel better or feels worse after 3 days.

What is in this leaflet:

1. What Ibuprofen 400 mg Soft Capsules is and what it is used for
2. What you need to know before you take Ibuprofen 400 mg Soft Capsules
3. How to take Ibuprofen 400 mg Soft Capsules
4. Possible side effects
5. How to store Ibuprofen 400 mg Soft Capsules
6. Contents of the pack and other information

1 What Ibuprofen 400 mg Soft Capsules is and what it is used for

Ibuprofen 400 mg Soft Capsules contains a medicine called ibuprofen. This belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) that work by relieving pain and fever.

Ibuprofen 400 mg Soft Capsules is indicated in adults and adolescents from 40 kg and above (12 years of age and above) for the relief of mild to moderate pain such as headache, acute migraine headaches with or without aura, muscular pain, period pain, feverishness and pain associated with a common cold.

2 What you need to know before you take Ibuprofen 400 mg Soft Capsules

Do not take Ibuprofen 400 mg Soft Capsules if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- ever suffered shortness of breath, asthma, runny nose, swelling or (itching) rash after you have used acetylsalicylic acid (aspirin) or other related painkillers (NSAIDs)
- have a history of gastro-intestinal bleeding or perforation related to previous NSAID therapy
- have (or have had two or more episodes of) a stomach ulcer or bleeding of the stomach
- suffer from a blood coagulation disorder or if you have another bleeding disorder
- suffer from severe liver, kidney or heart failure
- suffer from cerebrovascular or other active bleeding
- suffer from unclarified blood-formation disturbances
- suffer from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- are in the last 3 months of pregnancy
- are already taking other NSAID painkillers (including COX 2 inhibitors) or aspirin at doses above 75 mg daily

Do not use Ibuprofen 400 mg Soft Capsules in adolescents under 40 kg body weight and in children.

Warnings and precautions

Talk to your doctor before taking this medicine if you:

- suffer from Systemic Lupus Erythematosus (SLE) - a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorders of other organs - or a mixed connective tissue disease
- serious skin reactions have been reported in association with Ibuprofen 400 mg Soft Capsule treatment. You should stop taking this product 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.
- have hereditary blood formation disorder (acute intermittent porphyria)
- have or have ever had bowel problems or disease (ulcerative colitis, Crohn's disease)
- have or have had asthma or allergic disease as shortness of breath may occur
- suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria.
- are elderly, as you may be more likely to suffer from side effects
- suffer from kidney or liver disease
- have just had major surgery
- have swelling (oedema), high blood pressure (hypertension) or a heart disease
- are trying to become pregnant (ibuprofen belongs to a group of medicines, NSAIDs, that may impair fertility in women. The effect is reversible upon stopping the medicine).
- are in the first 6 months of pregnancy
- are taking low dose aspirin (up to 75 mg/day)
- have an infection - please see heading "Infections" below
- this medicine may contain traces of lecithin from soya bean. If you are allergic to peanut or soya, do not use this medicinal product.

Undesirable effects are minimised by using the minimum effective dose for the shortest period of time. 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 (Adults; 4 days for pain and 3 days for fever or migraine headaches. Adolescents; 3 days for pain, fever or migraine headaches).

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.

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.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen 400 mg Soft Capsules 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.
- During chicken pox (varicella) it is advisable to avoid use of Ibuprofen 400 mg Soft Capsules.

If you are taking Ibuprofen 400 mg Soft Capsules for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

In prolonged administration of Ibuprofen 400 mg Soft Capsules regular checking of your liver values, the kidney function, as well as the blood count, is required.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, you should stop taking this medicine and contact your doctor.

In general the frequent use of (several sorts of) analgesics can lead to lasting severe kidney problems. This risk may be increased under physical strain associated with dehydration. Do not take this medicine if you feel dehydrated.

There is a risk of renal impairment in dehydrated adolescents.

Infections

Ibuprofen 400 mg Soft Capsule may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 400mg Soft Capsules 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.

Other medicines and Ibuprofen 400 mg Soft Capsules

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

What should you avoid when you are taking this medicine?

Ibuprofen 400 mg Soft Capsules may affect or be affected by some other medicines.

For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidin),
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan).

Some other medicines may also affect or be affected by the treatment of Ibuprofen 400 mg Soft Capsules. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen 400 mg Soft Capsules with other medicines.

Do not use this medicine if you are taking:

- other NSAID painkillers (including COX-2 inhibitors).
- aspirin above 75 mg daily.

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

Especially if it regards one of the following medicines:

- **Low-dose aspirin** (up to 75 mg a day)
- **Diuretics** (drug to help you pass water)
- **Anticoagulants** e.g. warfarin, heparin and Anti-platelet drugs such as clopidogrel and ticlopidine (drugs that thin the blood)
- **Antihypertensives** (drugs used to treat high blood pressure e.g. captopril or propranolol)
- **Lithium, digoxin, phenytoin or Selective serotonin reuptake inhibitors** (SSRI's e.g. fluoxetine, - used to treat mood disorders)
- **Methotrexate** (used to treat rheumatoid arthritis, psoriasis and some cancers)
- **Zidovudine** (used to treat HIV)
- **Corticosteroids** (anti-inflammatory drugs, such as prednisone)
- **Ciclosporin or tacrolimus** (used to suppress the body's immune system)
- **Quinolone antibiotics** (used to treat a wide range of infections e.g. ciprofloxacin)
- **Probenecid and sulfapyrazone** (used to treat gout)
- **Moclobemide** (used to treat depression)
- **Aminoglycosides** (an antibiotic)
- **Cholestyramine** (used to reduce cholesterol)
- **Sulphonylureas** (used to treat diabetes)
- Any other **ibuprofen preparations or NSAID painkillers**, including those you can buy without a prescription.

Ibuprofen 400 mg Soft Capsules with food and drink

Ibuprofen 400 mg Soft Capsules may be taken on an empty stomach. However, a small number of people might experience mild indigestion with this medicinal product. If you experience mild indigestion, it is recommended to take this medicine with food or milk, to avoid gastrointestinal problems.

Some side effects, such as those affecting the gastrointestinal system can be more likely when alcohol is taken at the same time as Ibuprofen 400 mg Soft Capsules.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant, we do not recommend taking Ibuprofen 400 mg Soft Capsules. If you become pregnant during intake of Ibuprofen 400 mg Soft Capsules, stop taking this medicine and tell your doctor. Taking Ibuprofen 400 mg Soft Capsules, during pregnancy 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.

Breast-feeding

If you are breast-feeding, think that you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ibuprofen 400 mg Soft Capsules passes into breast milk, but may be used during breast-feeding at the recommended doses, for the shortest duration possible.

Fertility

This product belongs to a group of medicines

(NSAIDs) which might impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant however, talk to your doctor before using it if you have problems becoming pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines if you start to experience dizziness, drowsiness, vertigo or visual disturbances.

This medicine contains around 57.6 mg sorbitol.

This medicine may contain trace of lecithin from soya bean. If you are allergic to peanut or soya, do not use this medicinal product.

3 How to take Ibuprofen 400 mg Soft Capsules

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.

Adults and adolescents from 40 kg and above (12 years of age and above):

One Ibuprofen 400 mg Soft capsule up to 3 times a day, as required. Take only as much as you need to relieve your symptoms and leave at least 6 hours between each dose.

Do not take more than three Ibuprofen 400 mg Soft capsules in any 24 hour period.

Ibuprofen 400 mg Soft Capsules 400 mg is for oral use.

Ibuprofen 400 mg Soft Capsules should be swallowed unchewed with plenty of liquid.

This medicine is for short term use only.

The minimum effective dose should be used for the shortest time 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).

It is not recommended to use this medicine in children under 12 years of age or in children weighing less than 40 kg.

Adults: You must talk to a doctor if you do not feel better or if you feel worse after 4 days for pain or 3 days for fever and migraine headaches.

Adolescents (12 – 18 years old): You must talk to a doctor if the adolescent does not feel better or feels worse after 3 days.

Ibuprofen 400 mg Soft Capsules are contraindicated in adolescents under 40 kg body weight and in children.

If you take more Ibuprofen 400 mg Soft Capsules than you should

If you have taken more Ibuprofen 400 mg Soft Capsules 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 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 400 mg Soft Capsules:

Do not take 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, Ibuprofen 400 mg Soft Capsules 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

Ibuprofen 400 mg Soft Capsules, 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.

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- **Pass blood in your faeces (stools/motions)**
- **Pass black tarry stools**
- **Vomit any blood or dark particles that look like coffee grounds**
- **Unexplained wheezing, shortness of breath, skin rash (which may be severe and included blister or peeling of the skin), itching or bruising, light-headedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough water**
- **Stiff neck, headache, nausea, vomiting, fever and disorientation**
- **Swelling of the face**
- **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).**

STOP TAKING the medicine and tell your doctor if you experience:

- **Indigestion or heartburn**
- **Abdominal pain (pains in your stomach) or other abnormal stomach symptoms**
- **Yellowing of the eyes and/or skin**
- **Severe sore throat with high fever or unexplained bleeding, bruising and tiredness**
- **Hypersensitivity reactions with hives and itch, as well as asthma attacks.**

The following are side effects that may be experienced.

Common (may affect up to 1 in 10 people) side effects are:

- Stomach complaints, such as indigestion, acid burn, stomach pain and nausea, diarrhoea, vomiting, flatulence (wind) and constipation, and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people) side effects are:

- Headache, dizziness, sleeplessness, agitation, irritability and tiredness
- Visual disturbances
- Perforation or gastrointestinal bleeding, black stools and vomiting of blood, worsening of existing bowel disease (ulcerative colitis or Crohn's disease), gastritis
- Various skin rashes

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

effects are:

- Tinnitus (ringing in the ears)

Pain in the flanks and/or abdomen, blood in the urine, and a fever may be signs of damage to the kidneys (papillary necrosis). Elevated urea concentration in blood.

Very rare (may affect up to 1 in 10,000 people) side effects are:

- Exacerbation of infection-related inflammations (e.g. necrotising fasciitis), aseptic meningitis with neck stiffness, headache, nausea, vomiting, fever or consciousness clouding. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) appear to be predisposed
- Problems in the blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. If this happens you must stop taking this medicine immediately and consult a doctor
- Severe hypersensitivity reactions – signs could be: swelling of face, tongue and throat, shortness of breath, palpitations, severe shock. If one of these symptoms occurs, which can happen even on first use, the immediate assistance of a doctor is required
- Psychotic reactions, depression, nervousness
- Palpitations, heart failure, myocardial infarction
- Asthma, shortness of breath and wheezing
- Arterial high blood pressure
- Oesophagitis, pancreatitis, formation of intestinal diaphragm-like strictures
- Damage to the liver (first signs could be discoloration of the skin), acute hepatitis
- Severe forms of skin reactions including rash with redness and blistering, Stevens-Johnson syndrome and dead-tissue. Exceptionally, severe skin infection and soft tissue complications during chicken pox (varicella) infection
- Passing less urine than normal, swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure
- Low haemoglobin levels (anaemia)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Side effects with frequency 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 Ibuprofen 400 mg Soft Capsules if you develop these symptoms and seek medical attention immediately. See also section 2. Skin becomes sensitive to light.

Medicines such as Ibuprofen 400 mg Soft Capsules 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 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Ibuprofen 400 mg Soft Capsules

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.

This medicinal product does not require any special storage conditions.

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

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 400 mg Soft Capsules contains

The active substance is ibuprofen. Each capsule contains 400 mg of ibuprofen

The other ingredients are:
Macrogol 600
Potassium hydroxide
Purified water
Medium Chain Triglycerides
Isopropyl alcohol
Lecithin (soya bean)

Capsule shell

Gelatin
Sorbitol Liquid, Partially Dehydrated (E420)

Capsule printing

Opacode WB black NS-78-17821 *

*The ink contains: Black iron oxide, HPMC 2910/ Hypromellose 6CP

What Ibuprofen 400 mg Soft Capsules looks like and contents of the pack

Ibuprofen 400 mg Soft Capsules are clear oval transparent soft gelatin capsule with a logo printed in black ink.

Ibuprofen 400 mg Soft Capsules is available in PVC/PE/PVdC/Al blisters and in PVC/PE/PVdC/Al/PET blisters.

Pack of 4, 10, 12, 15, 16, 20 and 30 capsules. Not all pack sizes may be marketed.

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