

PACKAGE LEAFLET: INFORMATION FOR THE USER**Ibuprofen 400 mg capsule, soft**

For use in adults and adolescents from 40 kg and above (12 years of age and above)

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.

- 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.
- 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.

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1. What Ibuprofen 400 mg capsule, soft is and what it is used for
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1. What Ibuprofen 400 mg capsule, soft is and what it is used for

Ibuprofen 400 mg capsule, soft 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 capsule, soft 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 capsule, soft

Please read the following information.

Do not take Ibuprofen 400 mg capsule, soft 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 capsule, soft in adolescents under 40 kg body weight and in children.

Warnings and precautions

Talk to a pharmacist or your doctor before taking your 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
- suffer from serious skin reactions such as exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis. The use of Ibuprofen 400 mg capsule, soft should be stopped immediately at the first appearance of skin rash, mucosal lesions, or any other signs of allergic reactions
- 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)

Undesirable effects are minimised by using the minimum effective dose for the shortest period of time.

Medicines such as Ibuprofen 400 mg capsule, soft 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 (4 days for pain or 3 days for fever or migraine headaches). If you have heart problems, previous stroke or think 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.

During chicken pox (varicella) it is advisable to avoid use of Ibuprofen 400 mg capsule, soft.

In prolonged administration of Ibuprofen 400 mg capsule, soft regular checking of your liver values, the kidney function, as well as of 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.

The use of NSAIDs may mask the symptoms of infection.

Other medicines and Ibuprofen 400 mg capsule, soft

What should you avoid when you are taking this medicine?

Some medicines that are anti-coagulants (against clotting) (e.g. acetylsalicylic acid/aspirin, warfarin, ticlopidin), some medicines against high blood pressure (ACE-inhibitors e.g. captopril, betareceptor

blocking medicines, angiotensin II antagonists), and even some other medicines may affect or be affected by the treatment of ibuprofen. Seek therefore always advice of a doctor before you use ibuprofen 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 and 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 sulfinpyrazone** (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.

Seek therefore always advice of a doctor before you use ibuprofen with other medicines.

Ibuprofen 400 mg capsule, soft with food and drink

Ibuprofen 400 mg capsule, soft 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 capsule, soft.

Pregnancy, breast-feeding and fertility

Tell your doctor if you become pregnant during intake of Ibuprofen 400 mg capsule, soft.

If you are in the first six months of pregnancy talk to your doctor or a pharmacist before using Ibuprofen 400 mg capsule, soft.

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

If you are in the last three months of pregnancy do not use this medicine because it might cause problems to the unborn child or complications during delivery.

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.

Important information about some of the ingredients of Ibuprofen 400 mg capsule, soft

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these capsules.

3. How to take Ibuprofen 400 mg capsule, soft

Always take this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

For oral use.

For short term use only.

The minimum effective dose should be used for the shortest time necessary to relieve symptoms. 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.

Ibuprofen 400 mg capsule, soft should be swallowed unchewed with plenty of liquid. Ibuprofen 400 mg capsule, soft is contraindicated in adolescents under 40 kg body weight and in children.

The recommended dose for adults and adolescents from 40 kg and above (12 years of age and above) is: One capsule (400 mg ibuprofen) 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 capsules (1200 mg ibuprofen) in any 24 hour period.

If you take more Ibuprofen 400 mg capsule, soft than you should

If you accidentally take too many capsules, contact your doctor or hospital immediately. Bring the remaining capsules with you to show to the doctor. The symptoms of taking a lot more capsules than the stated dose (an overdose) include: nausea, stomach pain, vomiting containing either blood or brown grit (like ground coffee), diarrhoea, ringing in the ears, headache, dizziness, drowsiness, confusion, disorientation and rarely, loss of consciousness.

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 capsule, soft can cause side effects, although not everybody gets them.

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

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

The following frequencies are taken as a basis when evaluating side effects:

very common	affects more than 1 user in 10
common	affects 1 to 10 users in 100
uncommon	affects 1 to 10 users in 1,000
rare	affects 1 to 10 users in 10,000
very rare	affects less than 1 user in 10,000

The following are side effects that may be experienced.

Infections

Very rare: 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.

Blood disorders

Very rare: 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.

Problems of the immune system

Uncommon: Hypersensitivity reactions with hives and itch, as well as asthma attacks. You must stop taking Ibuprofen 400 mg capsule, soft and inform your doctor at once.

Very rare: 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.

Psychiatric disorders

Very rare: Psychotic reactions, depression, nervousness

Nervous system disorders

Uncommon: Headache, dizziness, sleeplessness, agitation, irritability and tiredness

Eye disorders

Uncommon: visual disturbances

Ear and balance disorders

Rare: Tinnitus (ringing in the ears)

Cardiac disorders

Very rare: palpitations, heart failure, myocardial infarction

Vascular disorders

Very rare: arterial high blood pressure

Respiratory, thoracic and mediastinal disorders

Very rare: Asthma, shortness of breath and wheezing

Stomach and bowel disorders

Common: 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: Perforation or gastrointestinal bleeding, black stools and vomiting of blood, worsening of existing bowel disease (ulcerative colitis or Crohn's disease), gastritis

Very rare: Oesophagitis, pancreatitis, formation of intestinal diaphragm-like strictures

Liver disorders

Very rare: Damage to the liver (first signs could be discoloration of the skin), acute hepatitis

Skin disorders

Uncommon: Various skin rashes

Very rare: 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.

Kidney disorders

Rare: 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: Passing less urine than normal, swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure.

Investigations

Very rare: Low haemoglobin levels (anaemia).

Medicines such as Ibuprofen 400 mg capsule, soft may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Ibuprofen 400 mg capsule, soft

This medicinal product does not require any special storage conditions.

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

Do not use Ibuprofen 400 mg capsule, soft 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 400 mg capsule, soft contains**

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

The other ingredients are:

Macrogol 600
Potassium hydroxide
Purified water

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 capsule, soft looks like and contents of the pack
Ibuprofen 400 mg capsule, soft is a clear oval transparent soft gelatin capsule.

Ibuprofen 400 mg capsule, soft is available in PVC/PE/PVdC/Al blisters.
Packs of 4, 10, 12, 15, 16 and 20 capsules.

Marketing Authorisation Holder and Manufacturer

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