

PATIENT INFORMATION LEAFLET

IBUPROFEN 400mg TABLETS

Please read all this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

WHAT IS IN YOUR IBUPROFEN 400mg TABLETS?

Ibuprofen 400mg Tablets are capsule shaped, white, film coated tablets, each containing Ibuprofen BP 400mg and the inactive ingredients Pregelatinised Starch, Maize Starch, Anhydrous Silicon Dioxide, Magnesium Stearate, Polyethylene Glycol and the colour Titanium Dioxide (E171).

Ibuprofen 400mg Tablets are in pack sizes of 12, 16, 21, 24, & 32 tablets.
Ibuprofen is a non-steroidal anti-inflammatory medicine.

WHO MAKES YOUR MEDICINE?

Product Licence Holder and Manufacturer of these Tablets is:

Max Remedies Ltd, William Nadin Way, Swadlincote, Derbyshire, DE11 0BB, UK

WHAT IS YOUR MEDICINE USED FOR?

Ibuprofen works by reducing the production of the chemical messengers in the body, which cause the sensations of swelling and pain. Ibuprofen therefore reduces the feeling of pain, swelling and stiffness and any accompanying fever.

Ibuprofen is useful for the relief of rheumatic and muscular pain, the pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, toothache, period pain, feverishness and the symptoms of cold and influenza.

BEFORE TAKING YOUR MEDICINE

Read the enclosed leaflet before taking this product. Do not take if you:

- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg

Speak to a pharmacist or your doctor before taking if you:

- have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems
- are a smoker
- are pregnant

If symptoms persist or worsen, consult your doctor.

You must consult your doctor if you are a adolescent between the age of 12 to 18 years and have been taking this medicinal product for more than 3 days or if your symptoms worsen.

Pregnancy and breastfeeding

Ibuprofen tablets are NOT recommended if you are pregnant or breastfeeding.

Ibuprofen 400 mg Tablets 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 400 mg Tablets, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Other medicines

Ibuprofen may affect how well other medicines work, when taken at the same time. If you take any of these types of medicines make sure that your doctor has taken this into account:

- Medicine for thinning the blood (anticoagulants).
- If you are taking other NSAID painkillers, or aspirin with a daily dose above 75mg.
- Medicines for high blood pressure (antihypertensives) including water tablets (diuretics).
- A medicine for epilepsy called Phenytoin sodium.
- Lithium
- Cyclosporin or Methotrexate.
- A heart medicine called Digoxin.
- Medicines for inflammation e.g. Steroids (Corticosteroids).
- Antibiotics containing Quinolone.
- Mifepristone (to induce early termination of pregnancy).
- Anti-platelet agents and serotonin reuptake inhibitors (SSRI's).
- Tacrolimus.
- Zidovudine.
- Anti-hypertensives.

Warnings:

Medicines such as Ibuprofen 400 mg Tablets 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 10 days. 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.

If affected by any of the following symptoms, do not drive or operate machinery:

Headaches, dizziness, problems with vision, drowsiness, confusions, ringing in the ears (tinnitus) and hallucinations.

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

HOW TO USE IBUPROFEN 400 mg TABLETS?

Ibuprofen Tablets should be swallowed whole with a glass of water or milk; it is best to take them with or after some food. The usual doses are given below:

Adults, the elderly and children over 12 years: This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Ibuprofen 400 mg Tablets for longer than 10 days unless your doctor tells you to do so.

The recommended dosage is: one tablet up to 3 times a day, as required. Leave at least 4 hours between each dose.

Do not exceed the stated dose.

If symptoms persist or worsen, consult your doctor.

POSSIBLE SIDE EFFECTS

Like many medicines, Ibuprofen may occasionally cause some unwanted effects. Most people using this medicine as directed by their doctor find it causes them no problems.

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
- Headaches

- Dizziness
- Drowsiness
- Confusions
- ringing in the ears (tinnitus)
- hallucinations

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
- Problems with your vision

Other unwanted effects may also include stomach upsets such as feeling sick (nausea), vomiting, diarrhoea, indigestion and stomach pains, unexplained wheezing or shortness of breath, skin rashes, itching, tingling sensations, bruising or facial swelling, fluid retention, nervousness, depression and insomnia.

- Medicines such as Ibuprofen 400 mg Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- If you experience any other side effects that trouble you, tell your doctor or pharmacist as soon as possible.
- If someone else has swallowed any of your tablets, immediately tell your doctor and contact your nearest hospital casualty department.
- If you forget to take a dose, take a dose as soon as you remember, but do not take more than the maximum dose per day.
- If you take too much Ibuprofen or you feel unwell after taking Ibuprofen, tell your doctor immediately or contact your nearest hospital casualty department.

REMEMBER: The chance of having an unwanted effect can be reduced by keeping the dose to the minimum number of tablets possible.

FURTHER INFORMATION

- Do not use after the expiry date.
- Keep out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.

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