

FLAT DIMENSION = 180 x 560mm
 FOLDED DIMENSION = 180 x 35mm

Package leaflet: Information for the user

IBUPROFEN TABLETS BP 400MG

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 doctor, pharmacist or nurse have 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

The active substance used in these tablets is Ibuprofen.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which helps relieve pain, reduces inflammation and lowers temperature when you have a fever.

These tablets are used for the relief of rheumatic and muscular pain, pain of non serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, and period pains. They are also used for the relief of feverishness, colds and influenza.

2. What you need to know before you take Ibuprofen Tablets

Do not take Ibuprofen Tablets if you:

- have ever been told you are allergic to ibuprofen, aspirin, other non-steroidal anti-inflammatory drugs, or to any of the other ingredients (listed in section 6).
- have a stomach ulcer, perforation or bleeding, or have had one twice or more in the past
- suffer from severe heart, liver or kidney problems
- are in the last 3 months of pregnancy
- have a condition which increases your tendency to 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 gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-inflammatory Drugs)
- have breathing difficulties
- have heart problems, high blood pressure or blood coagulation disorder.
- are under 12 years
- are taking other NSAID pain killers or more than 75mg aspirin a day.

Warnings and Precautions

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

- suffer from asthma, or have a past history of asthma
- have aseptic meningitis or other connective tissue diseases as Systemic Lupus Erythematosus (SLE - a condition of the immune system causing joint pain skin changes and other organ disorders)
- have a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) or suffer from bowel problems
- have kidney, heart or liver problems
- are elderly, as it increases the frequency of adverse reactions
- are in the first 6 months of pregnancy
- experience prolonged bleeding time
- have high cholesterol or previously have had a heart attack or stroke
- are a smoker
- you have an infection - please see heading "Infections" below.
- if you are taking Ibuprofen 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).
- 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.

There is a risk of kidney problems in dehydrated children and adolescents.

Take special care with this medicine:

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

Infections

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

Risk of heart attack or stroke:

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").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Women of childbearing age:

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.

Other medicines and Ibuprofen Tablets

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

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

- other painkillers, including non-steroidal anti-inflammatory medicines e.g. indometacin or diclofenac, and COX-2 inhibitors e.g. celecoxib
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- diuretics e.g. furosemide (drugs to increase urine output)
- corticosteroids (used to treat inflammatory conditions)
- methotrexate (used to reduce inflammation)
- lithium (used as a mood stabiliser)
- zidovudine (used in retroviral disease like HIV)
- selective serotonin reuptake inhibitors (SSRIs), e.g. fluoxetine (used for depression)
- ciclosporin or tacrolimus (given after transplant surgery, or used in psoriasis or rheumatism)
- mifepristone (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days
- quinolone antibiotics e.g. ciprofloxacin (for infections)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan) or drugs for heart disease or to stimulate your heart e.g. glycosides such as digoxin.
- cholestyramine
- sulphonyl ureas such as glibenclamide (to treat diabetes)
- aminoglycosides (a type of antibiotic)
- voriconazole or fluconazole (types of anti-fungal drugs)
- Ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen)

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

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 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. Do not take if you are breastfeeding. Speak to your doctor if you are in the first 6 months of pregnancy.

Ibuprofen Tablets contain Lactose, Sucrose, Sunset Yellow, Sodium and Sodium Benzoate

- If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product as it contains **Lactose** and **Sucrose**.
- Also **Sunset Yellow** (E110) used in this medicine may cause allergic reactions.
- This Medicine contains traces of sodium benzoate.

XXXXX

Information on sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take Ibuprofen Tablets

- Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.
- The tablets should be swallowed with a drink of water.
- Take with or after food to reduce the possibility of side effects.

This product is for short term use only. You should 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).

Adults, the elderly and children & adolescents between 12 and 18 years:

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

In children and adolescents between 12 and 18 years:

If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

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.

Do not give to children under 12 years of age.**If you take more Ibuprofen Tablets than you should**

If you have taken more Ibuprofen 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 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 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 be low blood pressure and reduced breathing.

If you forget to take a dose of Ibuprofen Tablets

If necessary, take the missed dose when you remember.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.

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 may sometimes cause side effects, although not everybody gets them.

If you experience any of the following serious effects then STOP taking this medicine immediately and contact your doctor or pharmacist:

- Peptic ulceration or perforation. Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools
- Inflammation of the brain lining. Symptoms could include stiff neck, headache, feeling or being sick, fever or feeling disorientated.

Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.

- Severe allergic reactions. Symptoms could include fainting, faster heart rate, swelling of the face, tongue and throat
- Worsening of asthma and wheezing or difficulty breathing
- 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 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).
- Ibuprofen, 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, light-headedness.
- Frequency Not known - 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 if you develop these symptoms and seek medical attention immediately. See also section 2.

Other possible side effects**Uncommon (may affect up to 1 in 100 people)**

- Allergic reactions such as hives, skin rashes and itching (or SLE)
- Abdominal pain, indigestion, heartburn and feeling sick
- Headache

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

- Diarrhoea, wind, constipation or being sick, chest pain or fast, irregular heartbeat.

Very rare (may affect up to 1 in 10,000 people)

- Reduction in blood cells, which can make the skin pale or yellow, cause fever, sore throat, mild mouth ulcers, flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose
- Nervousness, visual disturbance, ringing in the ears and dizziness
- Liver problems. Symptoms could include yellowing of the skin or the whites of the eyes
- 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)
- Kidney problems. Symptoms could include passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)

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

- Skin eruptions
- Skin becomes sensitive to light
- Worsening of asthma or bronchospasm
- Swelling (oedema), high blood pressure, heart failure or attack
- Worsening of colitis and Crohn’s disease
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Medicines such as Ibuprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

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

Reporting of side effects

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

can also report side effects directly via Yellow Card Scheme Website: 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.
- Blisters: Do not store above 25°C. Store in the original package. Containers: Do not store above 25°C. Keep the container tightly closed.
- Do not use this medicine after the expiry date (EXP.) 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: lactose, potato starch, hypromellose, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, sucrose, talc, pregelatinised starch, maize starch, titanium dioxide (E171), mastercote pink SP0478 (containing sucrose, titanium dioxide (E171), sunset yellow (E110), erythrosine (E127), sodium benzoate) and carnauba wax.

What Ibuprofen Tablets look like and contents of the pack:

- The tablets are round and pink sugar coated
- They are available in packs of 6, 12, 24, 25, 48, 56, 84, 96, 100 or 250 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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