IBUPROFEN 200MG TABLETS

PATIENT INFORMATION LEAFLET

Read this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.

IN THIS LEAFLET:

1. **What this medicine is for**
2. **Before you take the medicine**
3. **How to take the medicine**
4. **Possible side effects**
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1. WHAT THIS MEDICINE IS FOR

Ibuprofen 200mg Tablets contain ibuprofen, which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, swelling and high temperature.

This medicine is used to relieve:

- rheumatic and muscular pain, backache
- neuralgia (nerve pain)
- headache, migraine
- dental pain, period pain
- fever (high temperature)
- the symptoms of colds and flu.

2. BEFORE YOU TAKE THE MEDICINE

Do not take Ibuprofen 200mg Tablets if you:

- have or have had a stomach ulcer, perforation or bleeding of the stomach
- are allergic to ibuprofen, to any of the ingredients (listed in section 6), or to aspirin or other painkillers (an allergic reaction may be recognised as shortness of breath, runny nose, skin rash or itching)
- have kidney or heart failure or severe liver failure
- are taking more than 75mg of aspirin a day
- are in the last 3 months of pregnancy.

Warnings and precautions
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.
If you are taking Ibuprofen 200mg 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).

Skin reactions
Serious skin reactions have been reported in association with Ibuprofen 200mg Tablets treatment. You should stop taking Ibuprofen 200mg 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.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen 200mg Tablets if you:

- are elderly because you may be at more risk of having serious side effects, particularly stomach problems
- have or have suffered from asthma, or have allergies
- have liver or kidney problems
- have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pains, skin changes and problems with other parts of your body
- 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.
- have an infection – please see heading 'Infections' below.

Infections
This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

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

Other medicines and Ibuprofen 200mg Tablets

You must not take these tablets if you are taking certain other medicines – see section 2 'Do not take Ibuprofen 200mg Tablets if'.

Ibuprofen 200mg Tablets may affect or may 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, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- corticosteroids
- methotrexate (a medicine for cancer)
- cardiac glycosides (medicines used to treat heart failure)
- cyclosporin and tacrolimus (immunosuppressant medicines often used following organ transplants)
- mifepristone (a medicine used to terminate pregnancy – NSAIDs should not be used for 12 days after mifepristone)
- lithium (for depression or mental problems)
- zidovudine (a medicine to treat viruses)
- quinolone antibiotics (medicines used to treat bacterial infections).

Some other medicines may also affect or be affected by the treatment of Ibuprofen 200mg Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen 200mg Tablets with other medicines.

Pregnancy, breastfeeding and fertility
Do not take Ibuprofen 200mg 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 200mg 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 200mg 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. Talk to your doctor before taking Ibuprofen 200mg Tablets if you are breastfeeding.

Ibuprofen 200mg Tablets belong to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take these tablets occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

Important information about some of the ingredients of this medicine.
This product contains sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per 2 tablets, that is to say essentially 'sodium-free'.

3. HOW TO TAKE THE MEDICINE

Age	Dose and how often to take
Adults, the elderly and children over 12 years	Take 1 to 2 tablets up to 3 times a day, as required. Swallow tablets with a glass of water preferably with or after food. Do not take more often than every 4 hours. Do not exceed 6 tablets in 24 hours.
• This medicine is for short-term use only • Take the lowest effective dose for the shortest duration necessary to relieve symptoms **In Adults:** Do not take Ibuprofen 200mg Tablets for longer than 10 days unless your doctor tells you to. Talk to a doctor or pharmacist if you do not get better or get worse, or if new symptoms occur. **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.	
Do not give to children under 12 years.	

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

If you take more Ibuprofen 200mg Tablets than you should:

If you have taken more tablets 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.

4. POSSIBLE SIDE EFFECTS

Most people take Ibuprofen 200mg Tablets without any problems, but it can have side effects, like all medicines.

To reduce the chance of side effects, especially if you are elderly, use the lowest effective dose for the shortest possible time.

If you get any of the following at any time during your treatment STOP TAKING, and get medical help straight away:

Allergic reactions:

The following reactions may mean you are having an allergic reaction to this medicine:

- asthma, worsening of asthma, unexplained wheezing or shortness of breath
- swelling of the face, lips, tongue and throat (causing difficulty in swallowing or breathing)
- rapid heart rate, low blood pressure, collapse
- also, there may be skin reaction (including hives, rash and itching) – very rarely these can be severe with blistering and peeling skin.

Skin problems:

- A severe 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 200mg Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light – frequency unknown.

Stomach and bowel problems including:

- indigestion or heartburn
- pains in your stomach (abdomen) or other abnormal stomach problems
- pass blood in your stools or motions
- pass black tarry stools or motions
- vomit any blood or dark particles that look like coffee grounds
- worsening of bowel problems (ulcerative colitis or Crohn's disease).

Blood disorders which can cause:

- unexplained or unusual bruising or bleeding
- sore throat or mouth ulcers
- fever (high temperature)
- extreme paleness or weakness and exhaustion.

Heart and circulation effects: Medicines such as Ibuprofen 200mg Tablets may be associated with a small increased risk of heart attack (myocardial infarction), high blood pressure, heart failure, swelling due to fluid build-up (oedema) or stroke.

Other side effects that may occur include:

Other stomach and intestine effects including: diarrhoea, flatulence, constipation and vomiting.

Liver problems that might be indicated by yellowing of the skin and eyes (jaundice) and/or pale coloured stools and dark urine.

Kidney problems that might be indicated by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs) – very rarely kidney failure. Ibuprofen 200mg 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.

Nervous system problems including headache and aseptic meningitis (which can have symptoms such as severe headache, stiff neck, disorientation, fever and eye sensitivity to light in those with existing autoimmune disorders such as lupus).

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 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. STORING THE MEDICINE

Do not use after the expiry date shown on the pack.
Do not store above 25°C.
Store in the original container.
Keep out of the sight and reach of children.

6. FURTHER INFORMATION

What is in this medicine:
The active ingredient is: Ibuprofen 200mg per coated tablet.
The other ingredients are: Lactose, Starch, Hydroxy Propyl Methyl Cellulose, Sodium Starch Glycollate, Colloidal Anhydrous Silica, Magnesium Stearate, Sucrose, Talc, Titanium Dioxide (E171).

What this medicine looks like and contents of the pack
Ibuprofen 200mg Tablets are white, capsule-shaped, sugar-coated tablets.
This pack contains 16 tablets.

Marketing Authorisation Holder:
Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer:
Galpharm International Ltd., Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

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Other formats
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