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

This medicine is available without prescription. However, you still need to take Ibuprofen Tablets carefully to get the best results from it.

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

In this leaflet:
1. What Ibuprofen Tablets are and what they are used for
2. Before you take Ibuprofen Tablets
3. How to take Ibuprofen Tablets
4. Possible side effects
5. How to store Ibuprofen Tablets
6. Further information

1. WHAT IBUPROFEN TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Ibuprofen 200mg Tablets. They contain the active ingredient called Ibuprofen.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines are painkillers and reduce inflammation.

Ibuprofen 200mg Tablets are used for:

- Rheumatic or muscular pain
- Pain of non-serious arthritic conditions (characterized by pain and stiffness in your body)
- Back pain
- Neuralgia (painful disorder of the nerves)
- Headache including migraine
- Toothache
- Period pain
- Feverishness
- Symptoms of cold & influenza

2. BEFORE YOU TAKE IBUPROFEN TABLETS

Do not take Ibuprofen Tablets if you:

- are allergic (hypersensitive) to Ibuprofen or any of the other ingredients of Ibuprofen Tablets. See section 6.
- are allergic to Aspirin or other NSAIDs, like cyclooxygenase-2 specific inhibitor.
- suffer from asthma, especially if you also have frequent stuffed or runny nose or swelling of the inside of the nose.
- have swelling of the hands, arms, feet, ankles, or lower legs.
- develop hives (red and sometimes itchy bumps) on your skin after taking this medicine, Aspirin or any other NSAIDs.
- suffer from severe liver, kidney or heart disease. Medicines such as Ibuprofen 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. 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.
- have ever had a peptic ulcer (ulcer in your stomach or duodenum).
- have ever had bleeding in your digestive tract.
- get blurred or poorer vision, blind spots, or changes in colour vision.
Take special care with Ibuprofen Tablets if you:
• have a previous history of bronchial asthma or allergic disease.
• suffer from heart, liver or kidney problems
  There is a risk of renal impairment in dehydrated adolescents.
• suffer from high blood pressure
• have or ever had Crohn’s disease (inflammation of the digestive system) or ulcerative colitis (disease that causes ulcers in the lining of the rectum and colon)
• are having surgery, including dental surgery

Taking other medicines
You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Ibuprofen Tablets.

Examples of medicines that can affect Ibuprofen Tablets are:
• Anti-inflammatory pain killers
• Aspirin
• Warfarin to prevent blood clots
• Lithium to stabilise, normalise or even-out mood swings
• Medicines for high blood pressure
• Diuretics (water tablets)

Pregnancy and breast-feeding
Ibuprofen belongs to a group of medicines which may lower your chances of becoming pregnant. Do not take this medicinal product if you are in the last three months of pregnancy.

Consult your doctor if you are pregnant, you plan to become pregnant, or you are breast-feeding. If you become pregnant while taking ibuprofen, call your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Ibuprofen Tablets
This medicinal product contains Sucrose & 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.

3. HOW TO TAKE IBUPROFEN TABLETS

Always take Ibuprofen Tablets exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Swallow the tablets with water during or after meals.

The usual dose is:

Adults and children over 12 years:
The starting dose is 2 tablets, taken with a glass of water then 1-2 tablets every four hours. Do not take more than six tablets in any 24 hour period. The risk of side effects is greater in the elderly, so your doctor will give you the lowest dose possible, and take special care of you.

Children below 12 years: Not recommended.

If in adolescents (between 12 and 18 years) this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Ibuprofen Tablets are for short term use only. Take the lowest dose for the shortest time necessary to relieve your symptoms. Continuous use should not exceed 48 hours.

Ibuprofen may be associated with a small increase 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.

If you take more Ibuprofen Tablets than you should
If you or someone you know accidentally takes a lot more than the stated dose (an overdose), you should contact a doctor immediately or go to the nearest A&E department.

If you forget to take Ibuprofen Tablets
If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten tablet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen Tablets can cause side effects, although not everybody gets them.

If any of the following happens, stop taking Ibuprofen Tablets and tell your doctor immediately or go to the nearest hospital emergency department:

- Rare allergic (hypersensitive) reactions such as difficulty of breathing, wheezing or dizziness
- Skin reactions including paling of skin, rash, itching, hives, blisters, blood spots, swelling of the skin with weals and, less often, blistering skin diseases which may appear like a burn, or as a red/purple rash, or a scaly skin.
- Asthma attacks (condition that affects the airways of the lungs causing breathing difficulties) or worsening of asthma
- Sensitivity to light
- Stomach ulcers, bleeding, or holes in the stomach or intestine, High blood pressure, Fluid retention (particularly in the elderly), vomiting a substance that is bloody or looks like coffee grounds, blood in the stool, or black and tarry stools. The risk may be higher for people who are older in age.

Common (occurring in less than 1 in 10 patients)
- Nausea, Vomiting
- Gastro-intestinal:
  - Diarrhoea, Gas or Bloating, Constipation, Pain in abdomen or Upset stomach
- Worsening of ulcers in the lining of the rectum and colon
- Worsening of inflammation of the digestive system
- Inflammation or irritation of the lining of the stomach
- Indigestion
- Effects on heart:
  - Medicines such as Ibuprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke
- Hypertension

Uncommon (occurring in less than 1 in 100 patients)
- Effects on Kidney: Inflammation of kidney tissue, kidneys disorder causing them to leak large amounts of protein from the blood into the urine, kidney failure, appearance of blood in the urine.
- Effects on Liver: Abnormal liver function tests, swelling of the liver that makes it stop working well (hepatitis) and yellowing of skin and the whites of your eyes (jaundice)
- Effects on Nervous system and special senses:
  - Visual problems
  - Inflammation of eye nerve
  - Headache
  - Feeling of burning, itching, prickling or tingling in the skin
  - Aseptic Inflammation of the lining of the brain (With symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation) especially in patients with diseases like lupus erythematosus ( a condition in which immune system attacks healthy cells and tissues of many parts of the body),mixed connective tissue disease (overlap disease)
  - Nervousness, Depression, Confusion, Hallucinations
- Ringing in the ears
- Light-headedness (loss of balance)
- Feeling of general discomfort or uneasiness
- Sleeplessness
- Excessive Tiredness
- Drowsiness
- Effects on blood:
• Low platelet count
• Effected blood cell counts
• Failure of the bone marrow to produce sufficient blood cells for the circulation (Aplastic anaemia)
• Abnormal breakdown of red blood cells

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.

5. HOW TO STORE IBUPROFEN TABLETS

Keep out of the reach and sight of children.

Do not store the tablets above 25°C. Keep them in the original pack.
Do not take these tablets after the expiry date shown on the pack.
The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ibuprofen 200mg Tablets contain:
The active substance is Ibuprofen. The other ingredients are Colloidal Anhydrous Silica, Lactose, Povidone K25, Sodium Starch Glycollate, Maize Starch, Magnesium Stearate, Stearic Acid, Hydroxypropyl Methylcellulose, Polysorbat, Purified Talc Special, Red Iron Oxide, Titanium Dioxide (E 171), Polyethylene Glycol, Sucrose, purified water and industrial Methylated Spirit.

What Ibuprofen Tablets look like and contents of the pack:
Ibuprofen 200mg Tablets are pink, round, biconvex, film-coated tablets and packed in blister packs of 12, 24, 48 & 96 Tablets.

Marketing Authorisation Holder and Manufacturer:
Activase Pharmaceuticals Limited, 11 Boumpoulinas, 3rd Floor, 1060 Nicosia, Cyprus

PL 28444/0087

This leaflet was last revised in: December 2015