

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 or pharmacist 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 or pharmacist. 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 after 3 days for adolescents and after 10 days for adults.

What is in this leaflet

1. What Ibucalm 200mg tablets are and what they are used for
2. What you need to know before you take Ibucalm 200mg tablets
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1. What Ibucalm 200mg tablets are and what they are used for

Ibucalm 200mg tablets contain Ibuprofen which is a type of painkiller called a 'non-steroidal anti inflammatory drug' (NSAID). It is used to relieve rheumatic and muscular pain, backache, neuralgia, migraine, headache, dental pain, period pains, feverishness and the symptoms of cold and flu in adults, the elderly and children over 12 years old.

2. What you need to know before you take Ibucalm 200mg tablets

Do not take this medicine if you:

- are allergic to Ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- Have a history of allergy to aspirin, ibuprofen or NSAID's which includes attacks of asthma, swelling of the nose and throat, skin rashes or a runny nose.
- Have severe liver, kidney or heart problems.
- Are over six months pregnant
- Have an active or a history of recurrent peptic ulcers (more than two).
- Have a history of gastro intestinal bleeding or perforation related to the use of NSAID's.
- Are already taking aspirin at doses of above 75mg daily or taking any other NSAID's.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- Suffer from Systemic Lupus Erythematosus (SLE), a condition of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs.
- Have inflammatory bowel disease (e.g. Crohns disease, Ulcerative colitis) as it could get worse.
- Have kidney problems as these can get worse.
- Have a history of asthma or allergies.
- Have an infection - please see heading "Infections" below.

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 Ibucalm 200mg tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

If you are taking ibuprofen for longer than the recommended time or at higher than recommended doses, you are at risk of serious harm. These include serious harm 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 this medicine treatment. You should stop taking this medicine 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.

Heart Conditions

Anti-inflammatory pain-killer medicines such as ibuprofen 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 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') or think you may be at risk of these conditions (for example: if you have high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker) you should discuss your treatment with your doctor or pharmacist.

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 children and adolescents.

Other medicines and Ibucalm 200mg tablets

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

This medicine may affect or 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).

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

Tell your doctor or pharmacist if you are already taking any of the following medicines:

- Diuretics (such as furosemide and triamterene) or beta blockers (such as atenolol and propranolol) for high blood pressure.
- Blood thinning medicines that prevent blood clotting e.g. Warfarin
- Low dose aspirin (up to 75mg daily)
- Other medicines such as corticosteroids, antiplatelet agents, cardiac glycosides, selective serotonin reuptake inhibitors (SSRIs), methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine or quinolone antibiotics.

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.

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.

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.

Ibucalm 200mg tablets contain sodium

This medicine contains less than 1 mmol Sodium (23mg) per 320mg tablet, that is to say essentially 'sodium-free'.

3. How to take Ibucalm 200mg tablets

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

Ibuprofen is only for short term use. The lowest effective dose should be used for the shortest duration necessary to relieve 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 over 12 years

One or two tablets to be taken three times a day as required. These tablets should be taken with water. Leave at least four hours between doses.

Do not take more than 1200 mg (6 tablets) in any 24-hour period.

Use in children and adolescents

Do not give to children under 12 years old.

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

In adults

Do not take Ibuprofen for longer than 10 days. If the product is required for more than 10 days, or if the symptoms worsen consult your doctor or pharmacist.

If you take more Ibucalm 200mg tablets than you should

Seek medical attention IMMEDIATELY if you accidentally take too many tablets.

If you have taken more of this medicine 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 Ibucalm 200mg tablets

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 can cause side effects, although not everybody gets them.

Serious side effects

If you suffer from any of the below, at any time during your treatment, STOP TAKING the medicine and seek medical help:

- Liver, Kidney problems or difficulty urinating.
- Pass blood in your faeces (stools or motions).
- Pass black tarry stools.
- Vomit any blood or dark particles that look like coffee grounds.
- Breathing difficulties such as shortness of breath and wheezing that may lead to dizziness
- Swelling of the face, tongue or throat
- Skin reactions including itchy, patchy, red or raised skin rash and very rarely skin blistering or peeling
- Indigestion, heartburn or stomach pains
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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.

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 cell)

Ibuprofen, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect the proper removal of acids 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.

Frequency not known: a red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using this medicine if you develop these symptoms and seek medical attention immediately. See also Section 2.

Other side effects

Uncommon (may affect up to 1 in 100 people): Stomach pain or indigestion, feeling sick, headache.

Rare (may affect up to 1 in 1,000 people): Diarrhoea, flatulence, constipation and vomiting.

Very rare (may affect up to 1 in 10,000 people): Severe problems with your gut (bleeding, perforation, ulcer), worsening of ulcerative colitis and Crohns disease, kidney problems, liver disorders, changes in the blood which may lead to fever, sore throat, mouth ulcers, flu-like symptoms, tiredness and unexplained bleeding/bruising

Ibuprofen may slightly increase the risk of heart attack or stroke. If you experience any of these or any other side effects and they get serious, contact your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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. How to store Ibucalm 200mg tablets

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Store in the original pack.

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 Ibucalm 200mg tablets contains

Each tablet contains the active ingredient Ibuprofen 200mg.

The other ingredients are colloidal anhydrous silica, starch, povidone, croscarmellose sodium, microcrystalline cellulose, alginic acid, magnesium stearate, sodium lauryl sulphate, sodium starch glycollate, hypromellose (E464), glycerol, carmine (E120) and titanium dioxide (E171).

What Ibucalm 200mg tablets looks like and contents of the pack

Ibucalm 200mg tablets are pink, biconvex, round coated tablets.

Ibucalm 200mg tablets are available in packs of 24, 48 or 96 tablets.

Marketing Authorisation Holder and Manufacturer

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