

PATIENT INFORMATION LEAFLET
LIBROFEM 200 mg TABLETS
(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 or pharmacist has 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 contact a doctor if your symptoms worsen or do not improve

In this leaflet:

1. What Librofem Tablets are and what they are used for
2. What you need to know before before you take Librofem Tablets
3. How to take Librofem Tablets
4. Possible side effects
5. How to store Librofem Tablets
6. Contents of the pack and other information

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

The name of your medicine is Librofem 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. They can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, ankylosing spondylitis, swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

Librofem Tablets can also be used to treat other painful conditions such as Toothache, pain after operation, Period pain, Headache including migraine.

2. WHAT YOU NEED KNOW BEFORE YOU TAKE LIBROFEM TABLETS

Do not take Librofem Tablets if you:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? Librofem tablets may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.
- are allergic to Ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- Do you have, or have you previously had a stomach ulcer or other gastric complaint?
- Do not take Librofem if you currently have peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have two or more episodes of peptic ulcer, Stomach bleeding or perforation in the past.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from swelling and irritation inside the nose?
- Do you suffer from severe liver, kidney or heart disease?

Medicines such as Librofem 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. You should discuss your treatment with your doctor or pharmacist before taking Librofem Tablets 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),
- Have any kind of stroke or think that you might be at risk of these conditions e.g. if you have a family history of heart disease or stroke, or have high blood pressure, diabetes, high cholesterol or are a smoker.

- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Do you have chicken pox or shingles?
- Have you been told by your doctor that you have an intolerance to some sugars?
- Are you or your child dehydrated? As there is a risk of kidney damage in dehydrated children adolescents and the elderly.
- If you have an infection - please see heading 'Infections'.

Warnings and precautions

Talk to your doctor or pharmacist before taking Librofem.

Take special care with Librofem.

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 Librofem/Ibuprofen 200 mg 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).

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

Skin reactions

Serious skin reactions have been reported in association with Librofem treatment. You should stop taking Librofem 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.

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 Librofem/Ibuprofen 200 mg tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections

Librofem may hide signs of infections such as fever and pain. It is therefore possible that Librofem 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 medicines and Librofem Tablets

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

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine) some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin-II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with Librofem. You should therefore always seek the advice of your doctor or pharmacist before you use Librofem with other medicines. In particular you should Tell your doctor if you are taking any of the following medicine in addition to those mentioned above;

- diuretics (water tablets)
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen)

Alcohol: Librofem tablets may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Librofem tablets might make these side effects worse.

Pregnancy and breast-feeding

Do not take Librofem 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 Librofem 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, Librofem 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.

Driving and Using Machines: Librofem tablets may make you feel dizzy or drowsy. If the tablets affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Important information about some of the ingredients of Librofem 200mg 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. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE LIBROFEM TABLETS

Always take Librofem 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 after meals, water during.

Librofem Tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

DOSAGE:

The usual dose is:

Adults and children over 12 years:

The usual dosage is 600 to 1800 mg spread throughout the day. Your doctor may choose to increase this depending on what you are being treated for; but no more than 2400 mg should be taken in one day.

Children:

The usual daily dose is 20 mg per kg of bodyweight each day, given in divided doses. Librofem should NOT be given to children under the age of 12 years.

In cases of severe juvenile arthritis your doctor may increase the dosage up to 40 mg/kg in divided doses.

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, **tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine.** This risk may be increased if you are dehydrated.

The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Librofem. Tell your doctor if you have been having headaches while taking this medicine.

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).

If you take more Librofem Tablets than you should

If you have taken more Librofem 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 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 Librofem 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

As with all medicines, Librofem Tablets can cause side effects, although not everybody gets them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

Stop taking Librofem Tablets and seek immediately medical help if you experience:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.

- Signs of intestinal bleeding such as
- Passing blood in your faeces (stool/motions)
- Passing black and tarry stools
- vomiting any blood or dark particles that looks like coffee grounds.
- 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].
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

TELL YOUR DOCTOR AND STOP TAKING LIBROFEM TABLETS IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reactions).
- Loss of vision blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Server spreading skin rash (‘Stevens-Johnson Syndrome’, ‘toxic epidermal necrolysis’ and ‘erythema multiforme’, symptoms include severe skin rash, blistering skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)
- 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).
- Liver, kidney problems or difficulty urinating

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 and light-headedness.

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Medicines such as, Librofem Tablets have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as, Librofem Tablets have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.

Blood disorders such as reduction in blood cells and platelet counts – the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.

Librofem has also been shown to sometimes worsen the symptoms of Crohn’s disease or colitis.

Other side effects

Common (affects up to 1 in 10 people)

- feeling dizzy or tired
- diarrhoea, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (affects up to 1 in 100 people)

- feeling Drowsy
- feeling anxious
- feeling a tingling sensation or “pins and needles
- difficulty Sleeping
- hives
- skin becomes sensitive to light

- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- Ringing in the ears (Tinnitus)
- sensation of spinning (vertigo)
- mouth ulcers

Rare (affects up to 1 in a 1000 people):

- feeling depressed or confused

Very rare (affects up to 1 in 10,000 people):

- inflammation of the pancreas

Not known (cannot be estimated from the available data)

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 generalized exanthematous pustulosis).

Stop using Librofem if you develop these symptoms and seek medical attention immediately. See also section 2.

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 National reporting systems listed below:

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. HOW TO STORE LIBROFEM 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. CONTENTS OF THE PACK AND OTHER

INFORMATION What Librofem 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, Polysorbate, Purified Talc Special, Red Iron Oxide, Titanium Dioxide (E 171), Polyethylene Glycol, Sucrose, purified water and industrial Methylated Spirit.

What Librofem Tablets look like and contents of the pack:

Librofem 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:

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