

BiProfenid[®] LP 100mg

ketoprofen

Prolonged-release scored tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What BI-PROFENID LP 100 mg prolonged-release scored tablets are and what they are used for
2. What you need to know before you take BI-PROFENID LP 100 mg prolonged-release scored tablets
3. How to take BI-PROFENID LP 100 mg prolonged-release scored tablets
4. Possible side effects
5. How to store BI-PROFENID LP 100 mg prolonged-release scored tablets
6. Contents of the pack and other information

1. WHAT BI-PROFENID LP 100 mg prolonged-release scored tablets ARE AND WHAT THEY ARE USED FOR

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS (M: musculo-skeletal system)

This medicine contains ketoprofen, a nonsteroidal anti-inflammatory drug (NSAID). It is intended for use in adults (over 15 years of age) for:

- the long-term treatment of:
 - . certain types of chronic inflammatory rheumatism,
 - . certain types of severe osteoarthritis.
- the short-term treatment of:
 - . certain types of inflammation around the joints (tendonitis, bursitis, acute pain in shoulder),
 - . certain types of joint inflammation caused by crystal deposits, such as gout,
 - . acute osteoarthritic pain,
 - . acute lower back pain,
 - . acute pain related to nerve irritation, such as sciatica,
 - . trauma-related pain and edema.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BI-PROFENID LP 100 mg prolonged-release scored tablets

If your doctor has told you that you are intolerant to some sugars, consult him or her before taking this medicine.

Do not take this medicine in the following cases:

- after 5 full months of pregnancy (i.e. 24 weeks since last menstrual period),
- history of allergy to ketoprofen or to any other ingredients in the medicine, history of hypersensitivity reactions such as bronchospasm, asthma, rhinitis, hives or other allergic reactions to ketoprofen, or to a related medicinal product, particularly other non-steroidal anti-inflammatory drugs or aspirin. Severe anaphylactic reactions, rarely fatal, have been reported in patients with such a medical history.
- history of digestive tract bleeding or gastrointestinal perforation related to previous treatment with NSAIDs,
- active or recurrent digestive tract bleeding or ulcer,
- digestive tract bleeding, bleeding in the brain or any other active bleeding,
- serious liver disease,
- serious kidney disease,
- serious heart disease,
- allergy (hypersensitivity) to wheat, as the medicine contains wheat starch.

Take special care with BI-PROFENID LP 100 mg prolonged-release scored tablets

Special warnings

THIS MEDICINE MUST ONLY BE USED UNDER MEDICAL SUPERVISION.

Medicines such as Bi-Profenid LP 100 mg prolonged-release scored tablets may increase the risk of heart attack ("myocardial infarction") or stroke. The risk increases with the dose and duration of treatment.

If you have heart problems, if you have had a stroke or think you may have risk factors for this type of disorder (e.g. if you have high blood pressure, diabetes, high cholesterol or if you smoke), talk to your doctor or pharmacist. Do not exceed the prescribed dose or treatment duration.

Precautions for use

Since it may be necessary to adjust your treatment, it is important that you inform your doctor before taking Bi-Profenid LP 100 mg prolonged-release scored tablets if:

- you have a history of asthma associated with chronic rhinitis, chronic sinusitis or nasal polyps. Taking this medicine may induce breathing difficulties or an asthma attack, particularly in certain subjects allergic to aspirin NSAIDs (see Section "Do not take this medicine in the following cases"),
- you have heart disease (high blood pressure and/or heart failure), liver or kidney disease or if you retain water,
- you have coagulation disorders,
- you have a disease involving chronic inflammation of the intestine (such as Crohn's disease or ulcerative colitis),
- you have a history of digestive disorders (previous stomach or duodenal ulcer),
- you are currently being treated with other medicines that increase the risk of peptic ulcer or digestive bleeding, such as glucocorticoids, antidepressants (SSRIs, i.e. selective serotonin reuptake inhibitors), medicines that prevent the formation of blood clots such as aspirin or anticoagulants such as warfarin. In one of these cases applies to you, consult your doctor before taking Bi-Profenid LP 100 mg prolonged-release scored tablets (see Section "Taking or using other medicines"),
- you have a history of skin reactions on exposure to the sun or UV rays (tanning beds).

Taking this drug is not recommended if you have galactose intolerance, Lapp lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary disorders).

You may take this medicine if you have celiac disease. Wheat starch can contain gluten, but only traces, and is therefore considered safe for patients with celiac disease.

DURING TREATMENT, if you have:

- signs of infection or if your symptoms worsen, INFORM YOUR DOCTOR. As with any NSAID, ketoprofen can mask the symptoms (such as fever) of an underlying infection,
- signs indicating allergy to this medicine, particularly an asthma attack, hives or sudden swelling of the face and neck, STOP TREATMENT AND IMMEDIATELY CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE,
- digestive tract bleeding (expulsion of blood from the mouth or blood in stools, or dark stools), or gastrointestinal ulcer, STOP TREATMENT AND IMMEDIATELY CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE,
- vision disturbances (blurred vision), stop treatment and INFORM YOUR DOCTOR.

For women: Bi-Profenid LP 100 mg prolonged-release scored tablets can affect your fertility. Therefore, you should not take this medicine if you are planning to have a baby, if you are having difficulty conceiving or if you are undergoing fertility tests.

Elderly subjects and patients with a low body weight have a higher risk of experiencing side effects, in particular digestive bleeding, ulcers and perforations. In these patients, kidney, liver and cardiac function must be closely monitored, and the doses reduced.

This medicine contains a non-steroidal anti-inflammatory drug: ketoprofen.

You must not take this drug at the same time as other medicines containing non-steroidal anti-inflammatory drugs and/or aspirin.

Read the package leaflet of any other medicines you may be taking carefully to ensure that they do not contain non-steroidal anti-inflammatory drugs and/or aspirin.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, because some medicines should not be taken together and others require a change in dose when they are taken together.

Before taking Bi-Profenid LP 100 mg prolonged-release scored tablets, you must always inform your doctor or pharmacist if you are taking or being given one of the following medicines:

- acetylsalicylic acid (aspirin) or other NSAIDs,
- corticosteroids,
- oral anticoagulants such as warfarin, injectable heparin, anti-platelet agents or other thrombolytics such as ticlopidine,
- lithium,
- methotrexate,
- ACE inhibitors, diuretics, beta-blockers and angiotensin II receptor blockers,
- certain antidepressants (SSRIs),
- deferasirox,
- ciclosporin, tacrolimus,
- penmetrexed.

Pregnancy

During the first trimester of pregnancy (12 weeks of pregnancy, i.e. 12 weeks after the first day of your last period), your doctor may need to prescribe this medicine.

Between 2.5 and 5 full months of pregnancy (12 to 24 weeks), this medicine should only be taken if advised by your doctor, and only for a short time. Prolonged use of this medicine is strongly inadvisable.

After 5 full months of pregnancy (after 24 weeks), you should under no circumstances take this medicine, as its effects on your unborn baby may have serious consequences, in particular affecting the heart, lungs and kidneys, even after only one dose.

If you have taken this medicine when you were more than five months pregnant, talk to your obstetrician/gynecologist who will recommend appropriate monitoring.

Breast-feeding

This medicine passes into breast milk. As a precaution, you should avoid taking this medicine if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

In rare cases, this medicine may cause dizziness, drowsiness, seizures or vision disturbances. You should not drive or operate machines if any of these effects occur.

List of excipients with a specific effect

Lactose, wheat starch (gluten).

3. HOW TO TAKE BI-PROFENID LP 100 mg prolonged-release scored tablets

How many BI-PROFENID LP 100 mg prolonged-release scored tablets should be taken

Dosage may vary depending on the disease.
It ranges from one to two 100 mg tablets, i.e. 100 to 200 mg per day.
IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How long BI-PROFENID LP 100 mg prolonged-release scored tablets should be taken

Oral use.
Tablets are to be swallowed whole with a big glass of water, if possible with a meal or at least a snack.

How often BI-PROFENID LP 100 mg prolonged-release scored tablets should be taken

The daily dose should be taken in 1 to 2 divided doses.
IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How long BI-PROFENID LP 100 mg prolonged-release scored tablets should be taken

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

If you take more BI-PROFENID LP 100 mg prolonged-release scored tablets than you should

In the event of overdose or accidental poisoning, STOP TREATMENT AND CONSULT A DOCTOR IMMEDIATELY.

If you forget to take BI-PROFENID LP 100 mg prolonged-release scored tablets

Do not take a double dose to make up for a forgotten tablet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Medicines such as Bi-Profenid LP 100 mg prolonged-release scored tablets may increase the risk of heart attack ("myocardial infarction") or stroke.

In general, the frequency of undesirable effects is ranked as follows:

- Very common (affecting more than 1 person in 10),
- Common (affecting more than 1 person in 100 and less than 1 person in 10),
- Uncommon (affecting more than 1 person in 1 000 and less than 1 person in 100),
- Rare (affecting more than 1 person in 10 000 and less than 1 person in 1 000),
- Very rare (affecting less than 1 person in 10 000),
- Frequency unknown (cannot be estimated from available data).

The following allergic reactions may occur:

- skin reactions:
 - uncommon: skin rash, itching,
 - frequency unknown: hives, exacerbation of chronic hives;
- respiratory reactions:
 - rare: asthma attack,
 - frequency unknown: rhinitis, difficulty breathing, particularly in subjects allergic to aspirin or non-steroidal anti-inflammatory drugs;
- general reactions:
 - frequency unknown: sudden swelling of the face and neck (angioedema), and allergic shock.

The following effects may also occur:

- digestive disorders:
 - frequency unknown: digestive tract bleeding, digestive perforation (see Section "Precautions for use"). These effects are more common when higher doses are given over a long period of time.
- skin disorders:

- frequency unknown: skin reactions on exposure to the sun or UV rays (tanning beds), skin detachment which may rapidly and very seriously spread over the whole body (Stevens-Johnson and Lyell syndromes).
If any of these occur, stop treatment immediately and inform your doctor.

The following effects may also occur during treatment:

- digestive disorders:
 - common: nausea, vomiting, difficulty digesting, abdominal pain, stomach pain,
 - uncommon: diarrhoea, constipation, flatulence, gastritis,
 - rare: stomatitis, gastrointestinal ulcer, colitis,
 - frequency unknown: serious inflammation of the intestine, Crohn's disease.
- brain disorders:
 - uncommon: headache, dizziness, drowsiness,
 - rare: tingling and prickling sensations,
 - frequency unknown: seizures, mood disorders, taste disorders.
- ear disorders:
 - rare: ringing in the ears,
- eye disorders:
 - rare: vision disturbances (blurred vision),
- heart disorders:
 - uncommon: edema,
 - frequency unknown: high blood pressure, heart failure, vasodilation,
- skin disorders:
 - frequency unknown: hair or body hair loss.

- general disorders:
 - uncommon: fatigue,
 - rare: weight gain.
- changes in laboratory test results:
 - blood:
 - rare: anaemia due to bleeding, decrease in number of white blood cells,
 - frequency unknown: marked decrease in number of certain white blood cells, that can lead to serious infection (agranulocytosis), platelet depletion, bone marrow insufficiency.
 - liver:
 - rare: increase in liver enzymes, liver disease, elevated bilirubin.
 - kidney:
 - frequency unknown: hyperkalemia, kidney disease, kidney function problems.

IF ANY OF THESE OCCUR, **INFORM YOUR DOCTOR.**

If you notice any side effects not mentioned in this package leaflet, or if certain side effects become serious, please inform your doctor or pharmacist.

5. HOW TO STORE BI-PROFENID LP 100 mg prolonged-release scored tablets

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date that is stated on the outer packaging.

The expiry date refers to the last day of that month.

Store at a temperature no higher than 30°C.

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 Bi-Profenid LP 100 mg prolonged-release scored tablets contain

The active substance is:

Ketoprofen 100.00 mg
for one tablet

The other ingredients are:

White layer: lactose monohydrate, wheat starch, hydrated colloidal silica, gelatin, magnesium stearate.

Yellow layer: hydroxyethyl cellulose, calcium hydrogen phosphate dihydrate, riboflavin sodium phosphate (E 106), magnesium stearate.

What Bi-Profenid LP 100 mg prolonged-release scored tablets look like and contents of the pack

This medicine is supplied as scored tablets. Box of 20 tablets.

Marketing Authorization Holder and Operating Company

sanoï-aventis France
1-13, boulevard Romain Rolland
75014 Paris
France

Manufacturer

FAMAR LYON
29, avenue Charles de Gaulle
69230 Saint Genis Laval
France

This leaflet was last approved in November 2011.

THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of reach of children.