

## **PACKAGE LEAFLET: Information for the patient**

### **FANS**

Granules for oral solution – 80 mg

(Ketoprofen lysine)

**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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any other side effect not mentioned in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Fans is and what it is used for
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### **1. WHAT FANS IS AND WHAT IT IS USED FOR**

Fans contains the active substance ketoprofen lysine. Ketoprofen (as lysine salt) is a nonsteroidal anti-inflammatory drug (NSAID).

Fans is indicated in the symptomatic treatment of the inflammatory conditions associated with pain, like: rheumatoid arthritis, ankylosant spondilitis, arthrosis accompanied with pain, extra-articular rheumatism, post-traumatic phlogosis, phlogistic conditions accompanied with pain in odontoiatra, otorhinolaryngoiatry, urology and pneumology.

## **2. BEFORE YOU TAKE FANS**

### **Do not take Fans if you:**

- are hypersensitive to ketoprofen lysine, to the other anti-inflammatory drugs or to any of the excipients of Fans;
- have had a history of hypersensitivity accompanied with asthma attack, bronchospasm, acute rhinitis, urticaria, nasal polyps, angioedema, as a consequence of taking ketoprofen or any other drug with similar mechanism of action (eg. aspirin or any other nonsteroidal anti-inflammatory drug);
- have an active peptic ulcer / haemorrhage;
- have had a history of peptic ulcer, gastrointestinal haemorrhage, perforation or chronic dyspepsia as a consequence of the therapy with antiinflammatory drugs;
- have had a history of haemorrhage or recurrent peptic ulcer (two or more different episodes);
- have Crohn disease or ulcerative colitis;
- have had a history of bronchial asthma;
- have a severe hepatic, renal or cardiac failure;
- have haemorrhagic diathesis, other coagulation disorders or if you are being treated with an anticoagulant therapy;
- are in the last trimester of pregnancy (also in the first two trimesters, it should be possibly avoided) or breastfeeding.

### **Take special care with Fans**

Side effects may be minimised with the use of the minimal effective dose for the shortest time of use that is needed to control the symptoms.

Care should be taken in patients who concomitantly take drugs that may increase the risk for ulcer or haemorrhage like oral corticosteroids, anticoagulants like warfarin, selective serotonin reuptake inhibitors and oral antiaggregants like aspirin.

Patients who have or have had gastrointestinal diseases should be carefully monitored if gastrointestinal disorders appear, especially gastrointestinal heamorrhage.

The concomitant use of Fans with NSAIDs (nonsteroidal anti-inflammatory drugs), including cyclooxygenase-2 inhibitors, should be avoided.

During treatment with NSAIDs, gastrointestinal haemorrhage, ulcer or perforation that may be fatal, have been reported.

In elderly patients and in patients with a history of ulcer, especially if complications like haemorrhage or perforation have been reported, the risk for gastrointestinal haemorrhage, ulcers or perforation is higher with the use of high doses of NSAIDs. These patients should begin treatment with the lowest possible dose. The use of gastroprotective drugs (eg. misoprostol or the proton pump inhibitors) should be taken into consideration for these patients and for patients who take low doses of aspirin and drugs that may increase the risk for gastrointestinal disorders. Patients with gastrointestinal history, especially elderly patients, should talk to the doctor or pharmacist for every abdominal symptom (especially gastrointestinal haemorrhage), particularly in the initial phases of the treatment. Elderly patients have a high frequency of side effects to NSAIDs, especially gastrointestinal haemorrhage and perforations, that may be fatal. When a gastrointestinal haemorrhage or ulcer is verified in patients who take Fans, the treatment should be discontinued.

Severe skin side effects, some of them fatal, like exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis have been very rarely reported during the use of NSAIDs. In the initial phases of the treatment, patients are at a higher risk: in most of cases, the beginning of the side effects is noticed within the first month of treatment. Fans should be discontinued if rash, mucous lesions or every other hypersensitivity symptom appears.

At the beginning of treatment, patients who suffer from cardiac failure, cyrrhosis, nephrosis, chronic renal failure or patients who take diuretics, should carefully monitor the renal function. In these patients, ketoprofen administration may reduce blood flow in the kidney and cause renal failure.

Care should be taken in patients with positive anamnesis for hypertension and / or mild to moderate congestive heart failure, as during treatment with NSAIDs, water retention and oedema has been reported.

## Infections

The antiinflammatory, analgesic and antipyretic effects of ketoprofen, may mask the symptoms of infection, such as fever and pain. It is therefore possible that Fans 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.

In patients with hepatic disorders or history of hepatic diseases, the levels of transaminases should be periodically monitored, especially during long-term therapy.

During the use of ketoprofen, cases of jaundice or hepatitis have been reported.

Asthmatic patients accompanied with chronic rhinitis, chronic sinusitis and nasal polyps, are mostly exposed to the risk of allergy from aspirin or from NSAIDs.

The use of ketoprofen may cause asthmatic attack and bronchospasms, especially in allergic patients from aspirin or other NSAIDs.

Patients with uncontrolled hypertension, congestive heart failure, ischemic cardiopathy, peripheral arterial diseases and/or cerebrovascular diseases may be treated with ketoprofen only after they are carefully monitored. Before the beginning of a long-term treatment, care should be also taken in patients with risk factors for cardiovascular diseases (like hypertension, hyperlipidemia, diabetes mellitus, smoking).

In case blurred vision occurs, it is necessary to discontinue the treatment.

Care should be taken in patients who have or have had allergy.

Fans should be carefully used in patients with haemopoietic disorders, systemic lupus erythematosus and other connective tissue disorders.

Care should be taken in hepatic, renal, cardiac disorders and in predisposed conditions for fluid retention. In these cases, the use of Fans may cause renal function worsening and fluid retention.

The use of NSAIDs may reduce fertility. For this reason, its use in women who plan to get pregnant should be avoided. The use of Fans in women who have fertility problems or have undergone fertility surveys should be discontinued.

Fans may increase the risk for cardiac attack or stroke. This risk is more possible during the use of higher doses and during long - term treatment. The recommended dose should not be overpassed.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or may take other drugs, including those obtained without a prescription.

The following interactions regard nonsteroidal anti-inflammatory drugs in general.

- Nonsteroidal anti-inflammatory drugs: the concomitant administration of different NSAIDs may increase the risk for ulcers and gastrointestinal haemorrhage through synergic effect;
- Anticoagulants (heparin, warfarin): NSAIDs may increase the effect of anticoagulants, the risk for haemorrhage;
- Antiaggregants (ticlopidin, clopidogrel) and the selective serotonin reuptake inhibitors (SSRI): increased risk of haemorrhage because of the inhibition of the function of blood platelets and of the damage of the intestinal mucosa;
- Lithium: NSAIDs increase the plasmatic levels of lithium (reduction of its renal excretion), which may reach toxic levels; the dose of lithium should be adjusted during treatment with ketoprofen and with other NSAIDs;
- Methotrexate: reduction of the renal clearance of methotrexate (increased toxicity);
- Diuretics: increased risk for renal failure because of the reduction of renal flow caused from prostaglandin inhibition;
- ACE inhibitors and angiotensin II antagonists: in some patients with renal function disorders (dehydrated or elderly patients), the concomitant administration may worsen the renal function, that includes acute renal failure. Care should be taken in elderly patients. Patients should be adequately hydrated. Monitoring of the renal function after the beginning of therapy with Fans should be taken into consideration;
- Corticosteroids: increased risk for ulcer or gastrointestinal haemorrhage;
- Pentoxiphylline: increased risk for haemorrhage;
- Zidovudine: increased blood toxicity, with severe anemia that is manifested one week after the beginning of treatment with nonsteroidal anti-inflammatory drugs;
- Sulphonylureas: increased hypoglycemic effect of sulphonylureas;

- Antihypertensives (beta-blockers, ACE-inhibitors, diuretics): treatment with NSAIDs may reduce their antihypertensive effect;
- Cyclosporin and tacrolimus: increased risk of nephrotoxicity;
- Thrombolytics: increased risk for haemorrhage;
- Probenecid: increased plasmatic concentration of ketoprofen.
- Quinolone antibiotics: potentially increase the risk of seizures.

## **Pregnancy, breastfeeding and fertility**

### **Pregnancy**

Inform your doctor or pharmacist if you are pregnant or if you are planning to get pregnant.

It is advised to avoid nonsteroidal anti-inflammatory drugs during the first and second trimester, except cases when the potential benefit for the mother outweighs the potential risk to which the foetus is exposed.

Nonsteroidal anti-inflammatory drugs are contraindicated during the third trimester of pregnancy as their use is accompanied with the risk for fetal ductus arteriosus closure and the possibility of continuous pulmonary hypertension in the newborn. In addition, the onset of labour may be delayed and its duration may be increased.

### **Breastfeeding**

It is not recommended during breastfeeding.

### **Fertility**

Long-term use of some nonsteroidal anti-inflammatory drugs may decrease fertility in women.

This effect disappears when the treatment is stopped.

To be avoided in women with fertility problems.

### **Driving and using machines**

As ketoprofen may cause dizziness, drowsiness, vertigo and visual disturbances, care should be taken when driving and using machinery. If these symptoms appear, these activities should not be performed.

### **3. HOW TO TAKE FANS**

Always take Fans as your doctor told you. If you are not sure, contact with your doctor or pharmacist.

The recommended dose for adults is 1 sachet 80 mg, 3 times daily during meals.

In elderly patients, the dose should be given by the doctor.

Side effects can be minimized by using the lowest necessary effective dose to control the symptoms for the shortest period of time. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Patients with hepatic failure should take the lowest recommended effective dose.

Patients with mild to moderate renal failure should monitor the diuretic volume and the renal function before taking Fans.

#### **If you take more Fans than you should**

If you take more Fans or if the children have taken this drug by mistake, please contact your doctor, hospital, or call the emergency to take an opinion for the risk and advice for the actions to be taken.

#### **If you forget to take Fans**

If you forget a dose (or more doses), take the following dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for the forgotten dose (doses).

If you have any other question on the use of this medicinal product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all other drugs, Fans may cause side effects, although not everybody manifests them.

Nonsteroidal anti-inflammatory drugs may cause:

##### **Common (may affect up to 1 in 10 patients):**

- Nausea, vomiting, gastrointestinal discomfort.

##### **Uncommon (may affect up to 1 in 100 patients):**

- Headache, dizziness, drowsiness;
- Constipation, diarrhea;
- Rash;
- Swelling due to fluid accumulation (edema), fatigue;
- Paresthesia (tingling and numbness in hands and feet).

##### **Rare (may affect up to 1 in 1,000 patients) or very rare (may affect up to 1 in 10,000 people):**

- Hemorrhagic anemia (reduction in the number of red blood cells following bleeding);
- Blurred vision;
- Tinnitus (ringing in the ear);
- Asthma;
- Stomatitis (inflammation of the mouth), stomach or intestinal ulcer (peptic ulcer), colitis (inflammation of the colon);
- Hepatitis (inflammation of the liver), increased transaminases and bilirubin levels (alteration of certain blood tests useful to evaluate the function of the liver), jaundice (yellowing of the skin and the white part of the eyes);
- Pancreatitis (inflammation of the pancreas);
- Weight gain;
- Photosensitivity (sensitivity to light);
- Anaphylactic reactions including shock (severe allergic reactions).



**Frequency not known (frequency cannot be determined based on available data):**

- Thrombocytopenia (reduction in the number of platelets); agranulocytosis (reduction in the number of granulocytes, a type of white blood cell); bone marrow failure (reduced bone marrow activity); neutropenia (reduction in the number of neutrophils, a type of white blood cell);
- Depression (lowered mood), hallucinations, confusion, mood alterations, insomnia;
- Seizures;
- Dysgeusia (altered taste);
- Decreased appetite;
- Heart failure (reduced heart function);
- Hypertension (high blood pressure), vasodilation;
- Bronchospasm (constriction of the bronchi), rhinitis, dyspnea (difficult breathing);
- Chronic inflammatory bowel disease (worsening of colitis and Crohn's disease), gastrointestinal hemorrhage (bleeding of the stomach and intestines);
- Alopecia (hair loss); angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing and swallowing); Stevens-Johnson syndrome, Lyell's syndrome and toxic epidermal necrolysis (severe skin reactions);
- Kidney problems, such as acute renal failure, tubulo-interstitial nephritis, nephritic syndrome, nephrotic syndrome;
- Periorbital edema (swelling of the eye);
- Aseptic meningitis (inflammation of the meninges not caused by infection);
- Menometrorrhagia (prolonged or excessive uterine bleeding);
- Decreased female fertility;
- Optic neuritis (damage of the optic nerve due to inflammation).

Medicines such as Fans may be associated with an increased risk of heart attack (myocardial infarction) and stroke.

If you notice adverse effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. HOW TO STORE FANS**

Keep out of the reach and sight of children.

Do not use Fans after the expiry date which is stated on the package.

Store below 25°C.

Store in the original packaging to protect it from humidity.

## **6. FURTHER INFORMATION**

**What Fans 80 mg granules for oral solution contains**

**The active substance** is ketoprofen lysine salt.

Each sachet with granules contains 80 mg ketoprofen lysine salt equivalent to 50 mg ketoprofen.

**The excipients are:** mannitol, povidone, colloidal anhydrous silica, sodium chloride, sodium saccharin, ammonium glycyrrhizinate, peppermint oil.

**Content of the pack**

Carton box with 30 sachets.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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