

 **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 side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fans is and what it is used for
2. Before you take Fans
3. How to take Fans
4. Possible side effects
5. How to store Fans
6. Further information

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 spondylitis, arthrosis accompanied with pain, extra - articular rheumatism, post - traumatic phlogosis, phlogistic condition accompanied with pain in odontiatría, 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 other 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 recurrent haemorrhage or 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 taking an anticoagulant therapy;
- are in the last trimester of pregnancy (also in the first two trimesters, it should be possibly avoided) or breast - feeding.

Take special care with Fans

Side effects may be minimised with the use of the minimal effective dose for the shortest possible time 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, ulcer or perforation is higher with the use of high doses of NSAIDs. These patients should begin the 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 inform 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 epidermal toxic necrolysis have been very rarely reported during the use of NSAIDs. In the initial phases of treatment, patients are at a higher risk: in most of cases, the occurrence of side effects is noticed within the first month of the 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 the treatment with NSAIDs, water retention and oedema has been reported.

The antiinflammatory, analgesic and antipyretic effects of ketoprofen, may mask the symptoms of infection (eg. temperature). In patients with hepatic disorders or anamnesis of hepatic diseases, the levels of transaminases should be continuously monitored, especially during long - term therapy.

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

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

The use of ketoprofen may cause asthmatic crysis and bronchospasms, especially in patients allergic to 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 think 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 ictus. This risk is more possible during the use of higher doses and long - term treatment. The recommended dose should not be overpassed.

Taking other medicines

Talk to your doctor or pharmacist if you are taking, have recently taken or you 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): increase of the risk for 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 the 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 the renal blood 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 renal function, that includes a possible acute renal failure. Care should be taken in elderly patients. Patients should be appropriately hydrated. Monitoring of the renal function should be taken into consideration after beginning of therapy with Fans;
- Corticosteroids: increase the risk for ulcer or gastrointestinal haemorrhage;
- Pentoxifyllin: increased risk for haemorrhage;
- Zidovudin: increased blood toxicity, with severe anemia that is manifested one week before beginning the treatment with nonsteroidal anti - inflammatory drugs;
- Sulphonylureas: increased hypoglycemic effect of sulphonylureas;
- Antihypertensives (beta - blockers, ACE - inhibitors, diuretics): the 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.

Pregnancy, breast feeding 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 of closure of fetal ductus arteriosus 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.

Breast - feeding

It is not recommended during breast - feeding.

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 adjusted by the doctor.

Side effects can be minimized by using the lowest necessary effective dose to control the symptoms for the shorter period of time.

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

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

If you take more Fans than you should

If you take more Fans than you should 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 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:

- gastrointestinal disturbances like: discomfort, nausea, diarrhoea and sometimes, haemorrhage or ulcer;
 - hypersensitivity reactions that may appear like: rash, angioedema and bronchospasm;
 - renal failure (particularly in patients with renal damage); rarely, papillary necrosis or interstitial fibrosis can lead to renal failure;
 - other symptoms (more rare) like: headache, dizziness, nervousness, depression, photosiness, insomnia, vertigo, hearing disorders (like tinnitus), photosensitivity, haematuria, blood diseases, fluid retention (congestive heart failure is rarely observed), increased blood pressure, hepatic damage, alveolitis, pulmonary eosinophilia, pancreatitis, visual disturbances, Stevens-Johnson syndrome, toxic epidermal necrolysis.
- Rare cases of colitis (or worsening of the condition of colitis), Crohn's disease and aseptic meningitis have also been reported. Patients with connective tissue disorders (eg. with systemic lupus erythematosus) are particularly susceptible to these effects. 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 take Fans after the expiry date which is stated on the package!

Store below 25°C!

Store in the original packaging to protect it from light and humidity!

6. FURTHER INFORMATION

What Fans - Granules for oral solution 80 mg contain

The active substance is ketoprofen lysine salt.

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

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

Content of the pack

Carton box with 30 sachets.

Explanatory of the illustration icons on the packaging:

 Content.  Warning.  Granules.

Marketing authorisation holder and manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - Albania

This leaflet was formulated in April 2016.

 SPECIFICATION



CROPPING AREA 15 X 25 cm

PAY ATTENTION, all the layers are visible. If you have to print this document please check or uncheck the specific layers.