PACKAGE LEAFLET:
Information for the user

KETOFEX

Capsules – 1.38 mg
(Ketotifen fumarate)

Read all of this leaflet carefully before you start using 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 only. Do 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 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 KETOFEX IS AND WHAT IT IS USED FOR

Ketofex contains a medicine which is used for the prevention and treatment of allergic symptoms.
It is indicated in:
- allergic rhinitis and allergic skin diseases in terms of symptomatic treatment, when treatment with oral non-sedating antihistamines (antihistamines which do not cause drowsiness), and also local use of antihistamines and glucocorticoids, (cortisone preparations) is not appropriate;
- long-term prevention of asthmatic symptoms in combination with other anti-inflammatory drugs in patients with allergic polysymptomatics (e.g. allergic bronchial asthma and hay fever).

Note:
Ketofex capsules are not suitable for the treatment of acute asthma attacks.
A sole treatment of bronchial asthma with Ketofex - capsules is not recommended.
The therapy of severe asthma should be done gradually to be successful.
The therapy should be based on continous medical search.
Doctors estimate that in the progress of the disease and treatment success a daily self-control is important (e.g., through the recording of the measured respiratory burst with the peak-flow meter).
If there is no improvement even after following a correct therapy, the doctor should reassess the therapy.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE KETOFEX

Do not take Ketofex if you:
- are sensitive (allergic) to ketotifen, or to any of the other ingredients of the medicine (see also "Important information about some of the ingredients of Ketofex");
- suffer from epilepsy;
- are being treated with oral antidiabetics;
- are breastfeeding.

Take special care with Ketofex
- because Ketofex capsules are not suitable for prevention or treatment of acute asthma attacks; symptomatic and preventive asthma medicines that are already taken by the patient, should never be stopped abruptly when a long-term treatment with Ketofex is started. This is especially true for systemic corticosteroids because of the possible presence of adrenal insufficiency;
- thrombocytopenia may occur in patients taking Ketofex concomitantly with oral antidiabetic agents;
- because during treatment with Ketofex, seizures may occur very rarely; since Ketofex capsules can lower the seizure threshold, it should be used with caution in patients with epilepsy in the medical history;
- if the attention is impaired, possibly due to the sedative effect of Ketofex, the dose should be reduced.

Taking other medicines
Please, tell your doctor or pharmacist if you are taking / using, have recently taken / used any other medicines, including medicines obtained without a prescription.
The effect of the following medicines, or medicines belonging to the same group, may be affected by the concomitant use with Ketofex.
Ketofex may potentiate the effects of: CNS depressants, antihistamines, anticoagulants and alcohol.
Concomitant administration of oral hypoglycemic agents and Ketofex should be avoided (see "Take special care with Ketofex").
Ketofex increases the effect of bronchodilators; the frequency of their use should be reduced when co-administered with Ketofex.
Please, notice that these informations may be valid even if the drugs are used for short-treatment.

Taking Ketofex with food and drinks
Ketofex enhances the effect of alcohol. So, you should not consume alcohol while taking it.

Pregnancy and breastfeeding
Ask for medical advice before taking any drug.
Pregnancy
Although ketotifen (the active substance of Ketofex) had no effect on the pregnancy as well as the peri-and postnatal development in animal studies, its safety has not been established in humans.
Ketofex should therefore be administered to pregnant women only in compelling circumstances.

Breastfeeding
Ketotifen (the active substance of Ketofex) passes into the breast milk of rats. It is likely that this drug is excreted in human breast milk, therefore mothers who receive Ketofex should not breastfeed.

Driving and using machines
During the first days of treatment, Ketofex may affect your abilities to react. Ketofex, also when used according to the instructions, may change the abilities to react, use machines or work without secure hold.
You may become sleepy and slower than usual. You should not drive or work with machines until these side effects last.
This applies even more in combination with alcohol (see also "Taking Ketofex with food and drinks").

Important information about some of the ingredients of Ketofex
This medicine contains lactose. Please use Ketofex only after you have talked to your doctor whether or not you suffer from any intolerance to some sugars.

3. HOW TO TAKE KETOFEX

Always take Ketofex as prescribed by your doctor.
Contact with your doctor or pharmacist if you are not sure.

If not otherwise prescribed by your doctor, the usual dose is:
Adults, adolescents and children from 3 years during the first 3 - 4 days of treatment take in the evening 1 capsule (1 mg of ketotifen), then 1 capsule (1 mg of ketotifen) in the morning and evening.
If necessary, in adults, the maximum dose can be increased up to 2 capsules (equivalent to 2 mg of ketotifen) mornings and evenings.
The maximum daily dose is 4 capsules (equivalent to 4 mg ketotifen).

There are no data on the metabolism of Ketofex in patients with liver or renal impairments, therefore there are no dose adjustments.

Method of administration
Take Ketofex capsules with some liquid (e.g. tea or fruit juice).

Duration of administration
Always take Ketofex capsules as prescribed by your doctor.
Since the exertion of the full effect is to be expected after a treatment period of 8 - 12 weeks, the treatment should be carried out for long. This time should be respected even if you start feeling better.
A reduction of concomitant medications should be considered only after this period.
A particular limitation of the duration of use is not foreseen.
Please inform your doctor or pharmacist if you notice that the effect of Ketofex is too strong or too weak.

If you take more Ketofex
With Ketofex overdose may occur:
tiredness, drowsiness, confusion, dizziness, disorientation, slowed or accelerated heart rate, decreased blood pressure, accelerated breathing, shortness of breath, blue coloring of the skin and mucous membranes due to lack of oxygen in the blood, severe irritation or spasms (especially in the children), profound loss of consciousness (coma).
The treatment should be symptomatic. If the drug was taken recently, gastric lavage may be considered.
If you suspect for overdose, inform your doctor immediately, in order for him to decide what to do.

Medical measures taken in overdose
Depending on the degree of the overdose, the following measures should be taken:
- immediate gastric emptying through induced vomiting or gastric wash (especially if the drug is taken for a short time)
- reduction of absorption from the gastrointestinal tract using medical carbon
- acceleration of defecation through laxatives.

Ketotifen is not dialysable.

If necessary, symptomatic or specific treatment should include the following measures:
- monitoring of cardiovascular and respiratory function
- for anticholinergic effects, physostigmine
- in case of irritation or spasms, barbiturates or short-acting benzodiazepine can be used.

If you forget to take Ketofex
Do not take a double dose to make up a forgotten dose, but continue the treatment taking the prescribed dose at the right time.

If you stop taking Ketofex
The treatment with Ketofex should not be stopped, but it should be discontinued gradually over a period of 2 - 4 weeks, otherwise initial complaints may recur.
Please, talk to your doctor if for example because of side effects appearance you stop or end the treament with Ketofex before the usual time.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ketofex can cause side effects, although not everybody gets them.
In the evaluation of adverse reactions, the following frequency statements are used:

Very common	more than 1 patient of 10
Common	1 to 10 out of 100 patients
Uncommon	1 to 10 out of 1,000 patients
Rare	1 to 10 out of 10,000 patients
Very rare	less than 1 patient of 10,000
Not known	cannot be estimated

Possible side effects
Very common: tiredness (this effect may disappear with increasing duration of treatment).

Common: irritability, insomnia, nervousness, bronchial asthma worsening (in the beginning of treatment), dry mouth and nausea (these effects disappear with increasing duration of treatment).

Uncommon: weight gain because of appetite increase, cystitis.

Rare: sedation.

Very rare:
inflammatory diseases of the skin and mucosa, allergic diseases of the skin, severe skin reactions (erythema multiforme, Stevens-Johnson-syndrome), convulsions, elevated liver enzyme levels, liver inflammation (hepatitis).

Unknown:
disorders of CNS such as anxiety, aggressiveness, confusion, sleep disturbances mainly in children.
Allergic rash, urticaria.

Special instructions
If first signs of a hypersensitivity reaction appear, Ketofex should not be taken again. Tell your doctor in order for him to decide for the measures to be taken.
If you get any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KETOFEX

Keep away from children.
This medicinal product does not require special storage conditions.
Do not use the medicinal product after the expiry date which is stated on the package.

6. FURTHER INFORMATION

What Ketofex contains
The active substance is ketotifen fumarate.
1 capsule contains 1.38 mg ketotifen fumarate equivalent to 1 mg ketotifen.
Other ingredients: microcrystalline cellulose, lactose monohydrate, maize starch, talc, colloidal anhydrous silica, magnesium stearate, gelatin, titanium dioxide.

Contents of the pack: box with 20 or 30 capsules.

Explanation of illustrated icons in the packing:

Content. Warning! According to medical prescription! Capsules.

Marketing Authorisation Holder and manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.Fax: 00 355 4 23 62 800
Tirana - ALBANIA

This leaflet was last revised in August 2014.

SPECIFICATION

CROPING AREA 15 X 25 cm

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