

**i** **PACKAGE LEAFLET:**  
**Information for the user**

# KETOFEX

## Syrup – 1 mg / 5 ml

*(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 get 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
2. Before you take Ketofex
3. How to take Ketofex
4. Possible side effects
5. How to store Ketofex
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**1. WHAT KETOFE X IS AND WHAT IT IS USED FOR**

Ketofex syrup is 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 syrup is not suitable for the treatment of acute asthma attacks.

A sole treatment of bronchial asthma with Ketofex syrup 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.

If there is no improvement even after following a correct therapy, the doctor should reassess the therapy.

**2. BEFORE YOU TAKE KETOFE X**

**Do not take Ketofex if you:**

- are sensitive (allergic) to ketotifen, methyl – 4 hydroxybenzoate, propyl – 4 hydroxybenzoate, or to any of the other ingredients of the medicine;
- suffer from epilepsy;
- are being treated with oral antidiabetics;
- are breastfeeding.

**Take special care with Ketofex**

Ketotifen is not suitable for the 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 in steroid-dependent patients and in such cases the restoration of a normal pituitary-adrenal response to stress may take up to a year. Thrombocytopenia may occur in patients taking Ketofex concomitantly with oral antidiabetic agents. Concomitant use of these drugs should be avoided.

During treatment with Ketofex seizures have been reported very rarely.

Since Ketofex can lower the seizure threshold, it should be used with caution in patients with epilepsy in the medical history.

In diabetics, the carbohydrate content of the syrup (5 mL = 2.76 g carbohydrates) should be considered.

If the attention is impaired, possibly due to the sedative effect of Ketofex syrup , the dose should be reduced.

**Children**

In babies and young children the possibility of hereditary intolerance, unknown till now, to sorbitol and fructose should be considered.

**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.

Ketofex syrup may potentiate the effects of CNS depressants, antihistamines, anticoagulants and alcohol. Concomitant administration of oral hypoglycemic agents and Ketofex should be avoided.

Ketotifen 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 valide even if the drugs are used for short-treatment.

**Taking Ketofex with food and drinks**

Ketofex enhances the action of alcohol. So, you should not consume alcohol while taking it.

**Pregnancy and breastfeeding**

Pregnancy

Ask for medical advice before taking this drug.

Although ketotifen had no effect on the pregnancy as well as the peri-and postnatal development in animal studies, its safety in pregnancy has not been established in humans. Ketofex should therefore be administered to pregnant women only in compelling circumstances.

Breast-feeding

Ketotifen 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 with ketotifen you may feel weak. You may become sleepy and slower than usual. You should not drive or work with machines until these side effects last.

**Important information about some of the ingredients of Ketofex**

This medicine contains sorbitol. Please use Ketofex only after you have talked with your doctor whether or not you suffer from any intolerance to sugars.

Note for diabetic patients: 1 spoon of Ketofex syrup contains 2,65 g sorbitol (a source for 0,66 g fructose). Sorbitol may have a mild laxative effect.

Methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate can cause hypersensitivity and also delayed reactions. This medicinal product contains 2,4 vol.-% alcohol.

**3. HOW TO TAKE KETOFE X**

Always use Ketofex syrup as perscribed by your doctor. Contact with your doctor or pharmacist if you are not sure about the dose that you should take and when you should take it.

**If not otherwise perscribed by your doctor, the usual dose is:**

- infants from 6 months to 3 years: morning and evening 2.5 ml syrup (equivalent to ½ mg ketotifen);
- adults, adolescents and children from 3 years: during the first 3 - 4 days of treatment, evenings 5 ml (equivalent to 1 mg of ketotifen), then mornings and evenings 5 ml.

If necessary, in adults and children over 10 years, the maximum dose can be increased up to 10 ml syrup (equivalent to 2 mg of ketotifen) mornings and evenings.

The maximum daily dose is 20 ml syrup (equivalent to 4 mg ketotifen).

Medicines that contain alcohol are not recommended for the patients with liver impairments.

**Method of administration**

Take the syrup undiluted or with a little liquid (e.g. tea or fruit juice).

**Duration of administration**

Always take Ketofex syrup as perscribed 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.

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**

The main symptoms of an acute overdose are: drowsiness to severe sedation, dizziness, confusion and disorientation; tachycardia and hypotension; excitability or convulsions especially in children; reversible coma. The treatment should be symptomatic. If the drug was taken recently, gastric lavage may be considered.

The administration of medicinal charcoal may be useful. If necessary, symptomatic treatment and monitoring of cardiovascular functions are recommended. Upon excitation or convulsions, short-acting barbiturates or benzodiazepines can be administered. Ketotifen is not dialysable.

**If you forget to take Ketofex**

Do not take a double dose to make up a forgotten dose, but continue the treatment taking the perscribed dose in the right time.

**If you stop taking Ketofex**

Do not stop treatment with Ketofex without consulting a doctor. The treatment 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 treated person of 10
Common	1 to 10 out of 100 treated persons
Uncommon	1 to 10 out of 1,000 treated persons
Rare	1 to 10 out of 10,000 treated persons
Very rare	less than 1 treated person of 10,000
Not known	cannot be estimated

**Possible effects**

The side effects (Overview 1) are ranked by frequency, the most frequent first. Within each frequency grouping, the adverse reactions are ranked in order of decreasing severity.

**Overview 1:**

**Infections and parasitic diseases**

Uncommon: cystitis.

**Immune system disorders**

Very rare: erythema multiforme, Stevens-Johnson-syndrome, severe skin reaction.

Not known: methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate can cause hypersensitivity reactions and also delayed reactions.

**Metabolism and nutrition disorders**

Rare: weight gain.

**Psychiatric disorders**

Common: irritability, insomnia, nervousness.

**Nervous system disorders**

Uncommon: dizziness.

Rare: tiredness.

**Gastrointestinal disorders**

Uncommon: dry mouth.

**Hepatobiliary disorders**

Very rare: hepatitis, elevated liver enzyme levels.

Sleepiness and fatigue, dry mouth and dizziness may occur at the beginning of treatment, but usually disappear spontaneously with increasing duration of treatment. It has been reported nausea, vomiting, headaches, cramps, urticaria and rash. Symptoms of CNS stimulation such as agitation, confusion, insomnia and nervousness were observed especially in children. 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.

**Special instructions**

If first signs of a hypersensitivity reaction appear, Ketofex syrup should not be taken again. Tell your doctor in order for him to decide on measures to be taken.

**5. HOW TO STORE KETOFE X**

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 label and package.

**Instructions for storage after opening**

The medicinal product can be used 3 months after opening.

**6. FURTHER INFORMATION**

**What Ketofex contains**


The active substance is ketotifen fumarate.

5 ml syrup contain 1.38 mg ketotifen fumarate equivalent to 1 mg ketotifen.

Other ingredients: methyl – 4 hydroxybenzoate, propyl – 4 hydroxybenzoate, ethanol 96 %, sorbitol solution 70%, citric acid, disodium hydrogen phosphate, essence raspberry, purified water.

**Contents of the pack:** box with a bottle x 100 ml.


**Explanatory of the illustration icons on the packaging:**

 According to medical prescription.

 Content.  Warning.

 Syrup.

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

 **PROFARMA Sh.a.**  
Rruga "Myslym Keta"  
Tel.Fax: 00355 4 23 62 800  
Tirana - ALBANIA

**This leaflet was last revised in September 2012.**