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 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 syrup contains the active substance ketotifen fumarate, which is a medicine 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 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 allergic polysymptomatics (e.g. patients with 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 continuous 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 KETOFEX

Do not take Ketofex if you:

- are sensitive (allergic) to ketotifen, methyl-4 hydroxybenzoate, propyl-4 hydroxybenzoate, or to any of the excipients of the product;
- suffer from epilepsy;
- suffer from acute porphyria;
- 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.
It should be used with caution in patients with prostatic hypertrophy (adults), pyloroduodenal obstruction, urinary retention and in patients who have susceptibility to angle-closure glaucoma.
It should be avoided in patients with severe liver disease.
In diabetics, the content of sorbitol, which is a source of fructose, should be taken into account.
If the attention is impaired, possibly due to the sedative effect of Ketofex syrup, the dose should be reduced.

Children

In infants and young children the possibility of a hereditary intolerance to sorbitol and fructose, unknown until now, 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 this information 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

Pregnancy
Ask for your doctor or pharmacist’s advice before taking this drug.
Although there is no evidence of any teratogenic effect, recommendation for Ketofex in pregnancy cannot be given. Use of antihistamines in the latter part of the third trimester may cause adverse effects in neonates such as irritability, paradoxical excitability, and tremor.

Breastfeeding

Ketotifen is excreted in breast milk, therefore mothers who receive Ketofex should not breastfeed their child.

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 excipients of Ketofex

This medicine contains sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol can cause gastrointestinal discomfort and mild laxative effect. Please use this medicine only after your doctor has confirmed if you suffer from any sugar intolerance or not.

Note for diabetic patients:5 ml Ketofex syrup contains 2.8 g sorbitol (a source for approximately 0.7 g fructose).

Methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate may cause allergic reactions (possibly delayed).

This medicinal product contains alcohol (ethanol). Ethanol is harmful for those suffering from alcoholism. This should be taken into account in pregnant or breast-feeding women, children, high-risk groups such as patients with liver disease or epilepsy, all of them if they take a single dose of 5.2 ml syrup or more.

3. HOW TO TAKE KETOFEX

Always use Ketofex syrup as prescribed 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 prescribed by your doctor, the usual dose is:

- infants from 6 months (over 8 kg) to 3 years: 2.5 ml syrup (equivalent to ½ mg ketotifen) morning and evening;
- adults, adolescents and children over 3 years: during the first 3 - 4 days of treatment, 5 ml in the evening (equivalent to 1 mg of ketotifen), then 5 ml morning and evening.

If necessary, in adults, the maximum dose can be increased up to 10 ml syrup (equivalent to 2 mg of ketotifen) morning and evening.
The maximum daily dose is 20 ml syrup (equivalent to 4 mg ketotifen).
Medicines that contain alcohol are not recommended for patients with liver impairments.

Method of administration

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

Duration of administration

Always take Ketofex syrup 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 period of 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 prescribed dose at 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, you stop or end the treament with Ketofex before the usual time because of the manifested side effects.
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 out of 10
Common	1 to 10 out of 100 treated people
Uncommon	1 to 10 out of 1,000 treated people
Rare	1 to 10 out of 10,000 treated people
Very rare	less than 1 treated person out 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 infestations

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 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. Nausea, vomiting, headaches, cramps, urticaria and rash have been reported.
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/her to decide on measures to be taken.

5. HOW TO STORE KETOFEX

Keep out of the reach and sight of children.
Do not store above 25°C!
Do not use this medicinal product after the expiry date which is stated on the label and carton box.

6. FURTHER INFORMATION

What Ketofex contains
The active substance is ketotifen fumarate.
Each 5 ml of syrup contain 1.38 mg ketotifen fumarate equivalent to 1 mg ketotifen.

The excipients are: methyl-4 hydroxybenzoate, propyl-4 hydroxybenzoate, ethanol, sorbitol non-crystallising solution, citric acid, disodium hydrogen phosphate dihydrate, raspberry essence, purified water.

Contents of the pack: Box with an amber glass bottle of 100 ml.

Marketing Authorisation Holder (MAH) and Manufacturer

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Tirana, Albania.

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