

PACKAGE LEAFLET: Information for the user

KETOFEX

Hard capsules – 1 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 capsules are and what are they used for?
2. What you should know before you take Ketofex capsules?
3. How to take Ketofex capsules?
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1. WHAT KETOFEX CAPSULES ARE AND WHAT ARE THEY USED FOR?

Ketofex capsules contain ketotifen, a medicine which is used for the prevention and treatment of allergic symptoms.

They are 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 when local use of antihistamines and glucocorticoids (cortisone preparations) in allergic rhinitis 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 continuous medical controls. 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 CAPSULES?

Do not take Ketofex capsules if you:

- are sensitive (allergic) to ketotifen, or to any of the excipients of the medicine (see also “Important information about some of the excipients of Ketofex capsules”);
- suffer from epilepsy;
- suffer from acute porphyria;
- are being treated with oral antidiabetics;
- are breastfeeding.

Take special care with Ketofex capsules

- 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;
- if you suffer from prostatic hypertrophy (adults), pyloroduodenal obstruction, urinary retention or if you are susceptible to angle-closure glaucoma;
- if you suffer from severe liver disease.

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 capsules 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 capsules”).

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-term treatment.

Taking Ketofex capsules with food and drinks

Ketofex capsules enhance the effect of alcohol. So, you should not consume alcohol while taking them.

Pregnancy and breastfeeding

Ask for medical advice before taking any drug.

Pregnancy

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 receiving Ketofex should not breastfeed their child.

Driving and using machines

During the first days of treatment, Ketofex may affect your abilities to react. Ketofex capsules, 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 capsules with food and drinks”).

Important information about some of the excipients of Ketofex capsules

This medicine contains lactose. Please take Ketofex capsules only after you have talked to your doctor whether or not you suffer from any intolerance to some sugars.

3. HOW TO TAKE KETOFEX CAPSULES?

Always take Ketofex capsules 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 1 capsule (1 mg of ketotifen) in the evening, 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 capsules is too strong or too weak.

If you take more Ketofex capsules

With Ketofex capsules 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 convulsions (especially in 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 recently)
- 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 convulsions, barbiturates or short-acting benzodiazepines can be used.

If you forget to take Ketofex capsules

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 capsules

The treatment with Ketofex capsules 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 treatment 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 capsules 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:

anxiety, irritability, insomnia, nervousness, bronchial asthma worsening (in the beginning of treatment), nausea and headache (these effects disappear with increasing duration of treatment).

Uncommon:

cystitis, dry mouth, dizziness.

Rare:

sedation, weight gain because of appetite increase.

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).

Not known:

disorders of CNS such as restlessness, aggressiveness, confusion, sleep disturbances mainly in children.

Allergic rash, urticaria.

Special instructions

If first signs of a hypersensitivity reaction appear, Ketofex capsules 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 CAPSULES?

Keep out from the reach and sight of children.

Do not store above 25°C!

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

6. FURTHER INFORMATION

What Ketofex capsules contain

The **active substance** is ketotifen fumarate.

1 capsule contains 1.38 mg ketotifen fumarate equivalent to 1 mg ketotifen.

The **excipients** are:

Capsule content: microcrystalline cellulose, lactose monohydrate, maize starch, talc, colloidal anhydrous silica, magnesium stearate.

Capsule body: gelatin, titanium dioxide.

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

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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