Package leaflet: Information for the user

Bikarfen 50 mg tablets

Sequifenadini hydrochloridum

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
– 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bikarfen is and what it is used for

The active substance of Bikarfen 50 mg tablets, sequifenadine hydrochloride (hereinafter – sequifenadine), is an antihistamine agent which possesses also comparatively pronounced antiserotonin effect, that is essential in the treatment of allergic diseases.

Bikarfen is used in the following cases:
• acute and chronic allergic diseases: pollinosis (“hay fever”), allergic rhinitis, rinosinusopathy; allergic reactions induced by drugs, food-stuffs, chemicals, dust, animal hair, insect bites, air pollution or other allergens;
• itchy skin and other diseases with itching (allergic and atopic dermatitis, vasculitis, neurodermatitis, lichen planus, etc.) of allergic origin;
• allergy prophylaxis (before seasonal exacerbations) and supportive therapy.

2. What you need to know before you take Bikarfen

Do not take Bikarfen:
– if you are allergic to sequifenadine or any of the other ingredients of this medicine (listed in section 6);
– if you are pregnant;
– if you are breast-feeding;
– if you are taking medicines called monoamine oxidase (MAO) inhibitors.

Warnings and precautions
Patients with impaired kidney function should observe caution (see section 3). The medicine should be used cautiously in the presence of severe cardiovascular system, gastrointestinal or liver diseases.

Children
There are no clinical data on the use of this medicine in children.

Other medicines and Bikarfen
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Patients taking MAO inhibitors must not take antihistamines including sequifenadine (see *Do not take Bikarfen*).
Bikarfen does not increase the effect of sleeping pills.

Bikarfen with alcohol
Bikarfen does not increase depressant effect of alcohol on the central nervous system (CNS). However, it is not advisable to consume alcohol during the treatment.

Pregnancy and breast-feeding
This medicine must not be taken during pregnancy (see *Do not take Bikarfen*).
Antihistamines including sequifenadine must not be taken if you are breast-feeding (see *Do not take Bikarfen*). If the mother needs to be treated with Bikarfen, breast-feeding should be discontinued.

Driving and using machines
Patients who need rapid responses to perform their work (e.g. vehicle drivers) should determine before starting the treatment whether the medicine causes sedative effect or drowsiness. Individuals affected should avoid driving or perform work requiring agility and quick reactions, while on the treatment.

Bikarfen contains lactose
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Bikarfen

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Tablets are taken orally after meals with sufficient amount of water.

Adults
Acute and chronic allergic diseases: 50-100 mg (1-2 tablets) 2-3 times daily. The therapeutic effect is observed after 1-3 days. Usually, the treatment course is 5-15 days. If necessary, the treatment course may be repeated.

Allergy prophylaxis (before seasonal exacerbations) and supportive therapy: 50 mg (1 tablet) twice daily. The medication should be started 2 weeks before the expected allergic reaction.

Bikarfen tablets may be used alone (in monotherapy) or in combination with medications of local action (nasal drops, eye drops, ointments).

Patients with liver and/or kidney impairment
In patients with kidney impairment, the treatment should be initiated by using the lowest dose. Patients with liver disease, should exercise caution when using the medicine.

Elderly
There are no clinical data on the use of this medicine in the elderly.

If you feel that the effect of the medicine is too strong or too week, consult your doctor.

If you take more Bikarfen than you should
If you take more tablets than indicated, consult your doctor.
Symptoms: dryness of mucosal membranes, headache, vomiting, epigastric pain and other dyspeptic disorders.

If you forget to take Bikarfen
If you forget to take a regular dose, take it as soon as you remember. However, if it is near the time for your next dose, skip the missed dose and continue to take tablets as indicated by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bikarfen
If you have any questions on the use of this medicine, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (affects up to 1 in 10 people):
- drowsiness (dose-dependent). If the dose is 150 mg daily, drowsiness occurs less commonly. When increasing the dose to 400 mg daily, it occurs commonly. In most cases, drowsiness disappears after 2-5 days of treatment. Bikarfen can improve sleep in patients suffering from insomnia due to itching;
- mouth dryness.

Uncommon (affects up to 1 in 100 people):
- headache;
- weak epigastric pain, digestion disorders, in particular, when dosing on an empty stomach. The likelihood of these adverse reactions increases in patients with chronic gastrointestinal diseases. Adverse reactions disappear within the first days of treatment and there is no need to stop the use or significantly reduce the dose.

Rare (affects up to 1 in 1,000 people):
- decreased eosinophil leukocyte (specific white blood cell) count;
- agitation and insomnia (more commonly occur with high doses);
- light diuretic effect;
- menstrual disorders.

Very rare (affects up to 1 in 10,000 people):
- increased appetite.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the via the national reporting system.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bikarfen

Do not store above 25 °C.
Store in the original package in order to protect from light and moisture.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after "Expiry date". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Bikarfen contains
− The active substance is sequifenadine hydrochloride (*Sequifenadini hydrochloridum*).
Each tablet contains 50 mg of sequifenadine hydrochloride.

− The other ingredients (excipients) are: lactose monohydrate, microcrystalline cellulose, maize starch, silica colloidal anhydrous and magnesium stearate.

What Bikarfen looks like and contents of the pack
White or almost white, round flat tablets, with bevelled edge and score line on one side of the tablet. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

10 tablets in blister.
2 blisters (20 tablets) together with package leaflet in a cardboard box.

Marketing Authorisation Holder and Manufacturer
JSC Olainfarm
5 Rupnicu Str., Olaine, LV-2114, Latvia
Tel.: +371 67013701
Fax: +371 67013777
e-mail: olainfarm@olainfarm.lv

This leaflet was last revised in 10/2016