

Package leaflet: Information for the patient

Gistafen 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.

What is in this leaflet

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1. What Gistafen is and what it is used for

This medicine *Gistafen 50 mg tablets* contains sequifenadine hydrochloride, which belongs to a group of medicines called antihistamines that also possesses comparatively expressed anti-serotonin properties, which are essential in the treatment of allergic diseases.

Therapeutic indications:

- to relieve acute and chronic allergic diseases, such as:
 - pollenosis (“hay fever”); allergic rhinitis (runny nose); rhinosinusopathy;
 - food, drug, chemical or dust allergy;
 - allergy to sting and to animal;
 - allergy caused by air pollution or other allergen-induced allergy.
- to relieve allergy induced skin itching or itching caused by other diseases (e.g., allergic and atopic dermatitis, vasculitis, neurodermatitis, red flat lichen, etc.).
- allergy prophylaxis (before seasonal exacerbation) and supportive therapy.

2. What you need to know before you use Gistafen

Do not use Gistafen:

- if you are allergic to the medicine active substance or any of the other ingredients of this medicine;
- if you are pregnant;
- if you are breast-feeding.

Do not use Gistafen at the same time with MAO inhibitors (certain medicines used for treatment of depression).

Special precautions are necessary in such cases

Caution is required in patients with renal impairment (treatment starts with the lowest effective dose), severe heart and vascular (blood vessel) problems, gastrointestinal or liver diseases.

There are no clinical studies of the medicine use in children and the elderly.

Other medicines and Gistafen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Antihistamines including sequifenadine are contraindicated in patients taking monoamine oxidase inhibitors (MAO inhibitors).

Gistafen does not potentiate the central nervous system (CNS) inhibitory effects of sedatives and alcohol; however, during therapy it is advisable to avoid alcoholic beverages.

Gistafen with food and drink

Alcoholic beverages should be avoided during the therapy.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

You should not use Gistafen during pregnancy.

Antihistamines, including Gistafen, should not be taken during breast-feeding.

Driving and using machines

If this is the first time you are taking this medicine, check how you react first. Some people may be more sensitive to the medicine and should not drive or use machines if affected by drowsiness.

Important information about some of the ingredients of Gistafen

Each Gistafen tablet contains 302 mg of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Gistafen

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

Gistafen should be taken after meals with a sufficient amount of water.

Adults

Acute and chronic allergic diseases

The recommended dose is 50-100 mg 2-3 times per day. A therapeutic effect usually is obtained within 1-3 days following treatment initiation.

A treatment course of 5 -15 days is usual. If necessary the course of treatment may be repeated.

Prophylaxis (before seasonal exacerbation) and supportive therapy

The recommended dose is 50 mg twice a day. The medicine should be started 2 weeks prior to the expected allergic reactions.

Gistafen 50 mg tablets may be used alone or in combination with locally acting medicines (nasal drops, eye drops and ointments).

If you feel that the effect of Gistafen is too weak or too strong, please talk to your doctor or pharmacist.

If you take more Gistafen than you should

If you take too many *Gistafen* tablets, contact a doctor straight away. *Symptoms*: mucosal dryness, headache, vomiting, epigastric pain and other dyspeptic phenomena.

If you forget to take Gistafen

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

Such side effects as dry mouth or less frequently mild epigastric pain and dyspepsia are more possible when *Gistafen* dose exceeds 200 mg daily, especially, if you use the medication on an empty stomach. These undesirable effects may enhance in patients with chronic gastrointestinal diseases. In some cases the medicine can increase an appetite. Side effects disappear within the first few days of treatment and there is no need to significantly reduce the dose or discontinue *Gistafen*.

Eosinophil (special white blood cells) count decreased, mild diuretic effect, menstrual disorder headache are rarely observed as side effects.

Somnolence is dose-dependent. At the dose of 150 mg per day somnolence has occurred less frequently, when the dose was increased to 400 mg per day – more frequently. In most cases, somnolence disappears within 2-5 days of treatment.

Gistafen can improve sleep in patients suffering from insomnia due to itching.

Rare - agitation and insomnia, which are more possible if the high doses of medicine are used.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store *Gistafen*

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

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the package.

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 protect the environment.

6. Contents of the pack and other information

What *Gistafen* contains

Active substance: Sequifenadini hydrochloridum (Bicarphen) 50 mg.

Excipients: lactose, microcrystalline cellulose, maize starch, silica colloidal anhydrous and magnesium stearate.

What *Gistafen* looks like and contents of the pack

Description: white or almost white round, flat tablets with bevelled edges and break line on one side of a tablet.

Package: 10 tables in a blister; 20 tablets and the package leaflet in a carton pack.

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