

Package leaflet: Information for the user

Fenkarol 25 mg tablets

Quifenadine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2-3 days.

What is in this leaflet

1. What Fenkarol is and what it is used for
2. What you need to know before you take Fenkarol
3. How to take Fenkarol
4. Possible side effects
5. How to store Fenkarol
6. Contents of the pack and other information

1. What Fenkarol is and what it is used for

The active substance of Fenkarol is quifenadine hydrochloride (further in the text – quifenadine). It belongs to a group of medicines called antihistamines (to treat allergies). Unlike other conventional medicines of this group, quifenadine has dual mechanism of action. This explains the efficacy of medicine also in patients who do not respond to other antihistamines. Quifenadine has no pronounced depressant effect on the central nervous system. However, in some cases, a slight sedative effect can be observed.

Fenkarol is used to treat pollinosis (hay fever), acute and chronic urticaria, allergic rhinitis, allergic conjunctivitis, angioedema, dermatosis, eczema, neurodermatitis, itching, allergic reactions caused by food or medicines.

2. What you need to know before you take Fenkarol

Do not take Fenkarol

- if you are allergic to quifenadine or any of the other ingredients of this medicine (listed in section 6.);
- during the first 3 months of pregnancy; the administration is also not recommended during other periods of pregnancy;
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fenkarol:

- if you have severe cardiovascular system disorders;
- if you have severe gastrointestinal disorders;
- if you have severe liver and/or kidney disorders.

Children and adolescents

Fenkarol 25 mg tablets are not suitable for use in children less than 12 years of age.

Other medicines and Fenkarol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Fenkarol does not increase depressant effect of sleeping pills on the central nervous system. The medicine may decrease the gastrointestinal tract motility and increase the intestinal absorption of slowly absorbed medicines (e. g. medicines that prevent blood clot forming (coumarin group anticoagulants)).

Fenkarol with food and alcohol

Interactions with food have not been studied.

Fenkarol does not increase depressant effect of alcohol on the central nervous system.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You must not take Fenkarol tablets during the first 3 months of pregnancy. The administration is also not recommended during other periods of pregnancy (see “Do not take Fenkarol”).

It is not known whether quifenadine is excreted into breast milk. Therefore, you must not take this medicine while breast-feeding (see “Do not take Fenkarol”).

Driving and using machines

People who need rapid responses to perform their work (e.g. vehicle drivers) should determine, by taking the medicine for a short period before starting the treatment course, whether the medicine causes drowsiness. If this occurs, you should avoid driving while on the treatment.

Fenkarol contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fenkarol

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

Fenkarol tablets should be taken right after meals.

Adults: the dose is 25-50 mg 2-4 times a day. Maximum daily dose is 200 mg.

Adolescents (from 12 to 18 years of age): the dose is 25 mg 2-3 times a day.

The duration of treatment course is 10-20 days. If it is necessary, the course of treatment may be repeated.

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

If you take more Fenkarol than you should

If you take too much Fenkarol, consult the doctor. High doses may cause dryness of mucous membranes, headache, vomiting, pain in epigastrium and other digestive disorders.

If you forget to take Fenkarol

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

If you stop taking Fenkarol

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common (affects less than 1 people of 10)

- Dry mouth

Uncommon (affects less than 1 people of 100)

- Headache, drowsiness
- Gastrointestinal disorders (nausea, vomiting) that usually disappear when the dose is decreased or the medicine is withdrawn.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. How to store Fenkarol

Do not store above 25 °C. 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 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 protect the environment.

6. Contents of the pack and other information

What Fenkarol contains

- The active substance is quifenadine hydrochloride.
Each tablet contains 25 mg of quifenadine hydrochloride.
- The other ingredients are sucrose, potato starch, calcium stearate.

What Fenkarol looks like and contents of the pack

White or almost white, round flat tablets with bevelled edges.
10 tablets in blister from PVC film and aluminium foil.
2 blisters (20 tablets) together with the package leaflet in a cardboard box.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 10/2016