

## **Package leaflet: Information for the user**

### **Fenkarol 50 mg tablets**

Quifenadine

**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 has 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 (hereinafter referred to as quifenadine). It belongs to the group of medicines called antihistamines (medicines 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 marked depressant effect on the central nervous system. However, mild sedative effect could be observed in some cases.

The medicine is used to treat pollinosis (hay fever), acute and chronic urticaria (itchy rash), allergic rhinitis (snuffles), allergic conjunctivitis (inflammation of eye surface under the eyelids), angioedema (swelling of mouth, tongue, lips, throat, which may cause breathing and swallowing difficulties), skin lesions (dermatosis, eczema, neurodermatitis), skin itching, to treat 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 three months of pregnancy (the use 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 disorders;
- if you have severe gastrointestinal disorders;
- if you have severe liver and/or kidney disorders.

### **Children and adolescents**

Children and adolescents are recommended to use other Fenkarol dosage forms with a lower content of active substance per dosage unit.

### **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 hypnotics on the central nervous system. The medicine may decrease gastrointestinal tract motility and increase intestinal absorption of slowly absorbed medicines (e.g. medicines that prevent blood clots from forming in blood vessels (coumarin anticoagulants)).

### **Fenkarol with food and alcohol**

There are no food interaction studies.

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.

This medicine must not be taken during the first three months of pregnancy. It 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, this medicine must not be taken while breast-feeding (see “Do not take Fenkarol”).

### **Driving and using machines**

Patients whose professional skills need fast reaction to perform their work (e.g. vehicle drivers) should determine, by taking the medicine for a short period before the treatment course, whether the medicine causes drowsiness. Individuals affected should avoid driving while on the treatment.

### **Fenkarol contains sucrose**

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 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 should be taken right after meals.

For adults, the dose is 25-50 mg 2-4 times a day. Maximum daily dose is 200 mg.

For 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 necessary, the treatment course may be repeated.

In case 25 mg dosage is required, it is recommended to use Fenkarol 25 mg tablets.

If it seems to you 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 have taken more Fenkarol than you should, consult a doctor. High doses may cause dryness of mucous membranes, headache, vomiting, epigastric pain 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* (may affect less than 1 people in 10):

- dry mouth.

*Uncommon* (may affect less than 1 people in 100):

- headache, drowsiness;
- indigestion (nausea, vomiting) that usually disappear when the dose is decreased or the medicine is withdrawn.

**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 National Reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store Fenkarol**

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 carton after EXP. 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 (*Quifenadini hydrochloridum*). Each tablet contains 50 mg of quifenadine hydrochloride.
- Other ingredients are potato starch, sucrose, pregelatinized starch, calcium stearate.

### **What Fenkarol looks like and contents of the pack**

White or almost white, round, flat tablets with bevelled edges.

15 tablets per blister.

1 blister (15 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 02/2018**