

Package leaflet: Information for the user

ACTIFED 30 mg/1.25 mg/5 ml syrup
pseudoephedrine hydrochloride, triprolidine hydrochloride.

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.
- Ask your pharmacist if you need more information or advice.
- If any side effects occur, 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.

What is in this leaflet

1. What ACTIFED syrup is and what it is used for
2. What you need to know before you use ACTIFED syrup
3. How to use ACTIFED syrup
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1. What ACTIFED syrup is and what it is used for

ACTIFED syrup is indicated for the reduction of swelling of the nasal mucosa in case of rhinitis, including allergic rhinitis.

2. What you need to know before you use ACTIFED syrup

Do not use ACTIFED syrup:

- if you are allergic to pseudoephedrine, triprolidine, or any other ingredients of this medicine (listed in section 6);
- if you use (or have used during the past 2 weeks) antidepressants known as MAOIs (monoamine oxidase inhibitors); concomitant administration of these medicines may cause increase of blood pressure and/or development of hypertensive crisis;
- on children under 12 years of age.

Warnings and precautions

Talk to your doctor before using ACTIFED syrup:

- if you have cardiovascular diseases (especially coronary disease and high blood pressure),
- if you have diseases of the thyroid gland,
- if you have diabetes,
- if you have renal impairment,
- if you have a liver disease, moderate or severe renal failure,
- if you have urination disorders and/or prostate enlargement,
- if you have urinary retention,
- if you have glaucoma,
- if you have respiratory diseases, for example emphysema, chronic bronchitis, or acute or chronic bronchial asthma,
- if you use central nervous system inhibitors (incl. alcohol, sedatives, tranquilisers). During the use of this medicine, alcohol should be avoided and a doctor should be consulted before the use of CNS-inhibiting medications.
- if you give a urine sample, inform your doctor about the use of ACTIFED, as this can change the test results
- when using pseudoephedrine, sudden abdominal pain or bleeding from the rectum can be caused by inflammation of the colon (ischemic colitis). If you experience these gastrointestinal symptoms, stop using ACTIFED and contact your doctor immediately. See section 4.
- if you develop feverish redness (erythema) of the whole body with pustules (pustules). See section 4.

Actifed may cause a decrease in the blood supply to the optic nerve. If you experience sudden loss of vision, stop taking Actifed and contact your doctor or healthcare provider immediately. See section 4.

If you do not feel better or if you feel worse or new symptoms appear, you should stop taking this medicine and talk to a doctor.

ACTIFED syrup may cause somnolence.

Other medicines and ACTIFED syrup

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

Tell your doctor if you are using or have recently used:

- antidepressants, especially if you use monoamine oxidase inhibitors,
- medicines affecting the nervous system,
- medicines with a sedative effect.

ACTIFED syrup with food, drink, and alcohol

Alcohol should be avoided during the use of ACTIFED syrup, as it may strengthen the effect of ACTIFED that causes drowsiness.

Pregnancy and breastfeeding

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

ACTIFED syrup should not be used during pregnancy and breast-feeding, unless the doctor recommends it.

Driving and using machines

ACTIFED causes drowsiness and impairs the performance of activities requiring attention and reduces reaction speed.

Driving and operating moving machinery should be avoided until the individual effect becomes clear.

ACTIFED syrup contains sunset yellow FCF (E110), methyl parahydroxybenzoate (E218), sucrose, sodium benzoate (E211) and sodium

Sunset yellow FCF (E110) and methyl parahydroxybenzoate (E218) may cause allergic reactions (including delayed type).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains 7 g of sucrose per dose (10 ml in syrup). To be taken into consideration by patients with diabetes.

This medicine contains 10 mg of sodium benzoate per dose (10 ml in syrup), equivalent to 1 mg/ml.

3. How to use ACTIFED syrup

Always use 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.

The package contains a measuring spoon.

Adults and children over 12 years

10 ml (2.5 mg of triprolidine hydrochloride and 60 mg of pseudoephedrine hydrochloride) every 4–6 hours up to 4 times a day.

ACTIFED syrup is not recommended to be used for more than 5 consecutive days in children over 12 years of age without a doctor's respective recommendation. If the condition of a child over 12 years of age becomes worse during the treatment, contact a doctor.

Children under 12 years

ACTIFED syrup is not suitable for children under 12 years of age.

If you forget to take ACTIFED syrup

If you forget to take your dose, take it as soon as possible, but do not take a double dose.

If symptoms persist, contact your doctor.

If you take more ACTIFED syrup than you should

This medication must be stored away from the reach of children. Contact your doctor if you suspect overdose. Take this medicine or the package with you to the doctor's, so that the doctor knows which drug you have used.

4. Possible side effects

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

Very rare adverse effects (< 1/10,000), including individual cases:

- anxiety, euphoria, hallucinations, visual hallucinations, restlessness;
- headache, paresthesia (sensitivity disorder), psychomotor hyperactivity, drowsiness, tremor (trembling);
- cardiac arrhythmias, palpitations, fast heartbeat;
- feeling of nervousness, tiredness;
- hypersensitivity;
- nosebleed;
- abdominal discomfort, vomiting;
- reddened scaling skin rash with subcutaneous nodules and blisters, swelling of the skin, itching, rash, urticaria;
- difficult urination, urinary retention;
- increased blood pressure.

Unknown (incidence cannot be estimated from available data):

- sensitivity disorders, shaking, cerebrovascular event
- anxiety
- inflammation of the colon due to inadequate blood supply (ischemic colitis)
- unexpected fever and redness of the skin with small pustules
- decreased blood supply to the optic nerve (ischemic neuropathy of the optic nerve)
- myocardial infarction

Reporting of side effects

If any side effects occur, 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 www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ACTIFED syrup

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

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date signifies the last date of the 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 ACTIFED syrup contains

- The active substances are pseudoephedrine hydrochloride and triprolidine hydrochloride. 5 ml of syrup contains 30 mg of pseudoephedrine hydrochloride and 1.25 mg of triprolidine hydrochloride.
- The other excipients are: sucrose, glycerol, methylparaben (E218), sodium benzoate (E211), quinoline yellow (E104), sunset yellow FCF (E 110), purified water.

What ACTIFED syrup looks like and contents of the pack

ACTIFED syrup is a transparent yellow syrup.

Package contains 100 ml of syrup in an amber glass (type III) bottle with a metal screw cap and a measuring spoon with two ends (2.5 ml / 5 ml).

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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