

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

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. Do not pass it on to others.

It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

RHINOZAD, 2,5 mg + 60 mg, tablets triprolidine, pseudoephedrine

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1. What is medicine RHINOZAD and what it is used for?

This medicine is used to relieve the symptoms of colds, flu and allergies including runny nose, watery eyes, nasal congestion and blocked sinuses. The tablets contain pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes. This medicine is for use by adults and children aged 12 years and over.

2. Before you take RHINOZAD tablets

This medicine is suitable for most adults and children aged over 12 years but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not take RHINOZAD tablets:

- If you have ever had a bad reaction to any of the ingredients.
- If you have an overactive thyroid gland.
- If you have glaucoma (increased pressure in the eye).
- If you have prostate problems (difficulty with passing water or needing to pass water often).
- If you have very high blood pressure or severe heart disease.
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are taking furazolidone (an antibacterial agent).
- If you are taking sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).

If any of these apply to you, **get advice from a doctor or pharmacist without taking RHINOZAD tablets.**

Take special care with RHINOZAD tablets

- If you have liver or kidney problems.
- If you have high blood pressure or heart disease.
- If you have diabetes or if you been told by your doctor that you have an intolerance to some sugars.
- If you are taking alcohol.
- If you have epilepsy.

Taking other medicines

Tell you doctor or pharmacist if you are taking any **other medicines** (or have recently taken) including those obtained without a prescription, including:

- Sedatives and tranquilisers (drugs used to treat anxiety and tension).
- Antihypertensives (drugs used to treat high blood pressure such as guanethidine, methyl dopa, alpha and beta blockers, debrisoquine, bretylium and betanidine).
- Sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).
- Tricyclic antidepressants (used to treat mood disorders).
- Halogenated anesthetics (chloroform, cyclopropane, halothane, isoflurane or enflurane)
- If you have respiratory conditions such as emphysema (breathlessness, cough-variant), chronic bronchitis or acute or chronic bronchial asthma)

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist. If any of these bullet points apply to you now or in the past, talk to a doctor or pharmacist.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

Driving and using machines:

Δ Trigon. This medicine may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

Other important information about some of the ingredients of RHINOZAD tablets

RHINOZAD tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **RHINOZAD**.

3. How to take RHINOZAD

RHINOZAD tablets use exactly as directed in this leaflet. Please check with your doctor or pharmacist, If you are not sure. For oral use only.

Children aged 12 years or under

This medicine is not recommended for children aged 12 years or under.

Adults and children over 12 years old

One tablet every 4 - 6 hours, up to 4 times a day.

Leave at least 4 hours between doses.
Do not give more than 4 doses in 24 hours.
If symptoms persist talk to your doctor.

If you take more RHINOZAD than you should

If anyone has taken too many tablets contact a doctor or your nearest Accident and Emergency Department (Casualty) taking this leaflet and pack with you.

If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

4. Possible side effects

RHINOZAD tablets can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using this medicine and talk to your doctor:

- A few people have had hallucinations, but this is rare.
- High fever
- Epilepsy, tremor
- Occasionally people get skin rashes that are sometimes itchy.
- A few people may find their heartbeat increased.
- A few men, especially men with prostate problems, may have trouble passing water.

Other effects which may occur include:

Common side effects (may affect up to 1 in 10 people)

- restlessness,
- having trouble getting to sleep or bad dreams.
- Drowsiness.
- Dry mouth
- Nausea

Frequency not known:

- A sense of concern
- Euphoric mood
- Headache
- Gambling and loss of feeling in the arms and legs
- Psychomotor hyperactivity (in children)
- Drowsiness
- Change the heart rate
- Palpitations (increased heart rate)
- Dry throat
- Bleeding from the nose
- Dry nose
- Abdominal discomfort
- Vomiting
- Scabies
- Ospa with itching
- Pain while urinating
- Nervousness
- Tiredness
- High blood pressure.

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

5. How to store RHINOZAD tablets

Store below 25°C.
Store in the original package to protect from light and moisture.
Keep the product out of the reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What's in this medicine?

The active ingredients in RHINOZAD tablets are:

Pseudoephedrine hydrochloride 60 mg and triprolidine hydrochloride 2.5 mg in each tablet.

Other ingredients are: Lactose monohydrate, pregelatinised maize starch, povidone and magnesium stearate.

Contents of the pack:

RHINOZAD, 2.5mg + 60mg, tablets - uniformed, rounded, white, slightly biconvex tablets with break line on one side, available in packs of 1000 (100 x 10) tablets in blister packs, in a box.

Product Licence holder:

ZADA Pharmaceuticals Ltd.
Donji Bistarac bb
75 300 Lukavac BiH

Manufacturer:

ZADA Pharmaceuticals Ltd.
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75 300 Lukavac BiH