

PACKAGE LEAFLET: INFORMATION FOR THE USER

VASOFLEX

1 mg and 2 mg Tablets

PRAZOSIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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?

1. What Vasoflex is and what it is used for
2. Before you take Vasoflex
3. How to take Vasoflex
4. Possible side effects
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1. WHAT VASOFLEX IS AND WHAT IT IS USED FOR?

Vasoflex is one of a group of medicines called alpha-blockers.

It is usually used to treat high blood pressure (hypertension). It may also be used to treat heart failure, painful cold fingers (Raynaud's Disease) or mild enlargement of the prostate gland (prostatic hyperplasia) in men.

In patients with high blood pressure (hypertension) Vasoflex works by relaxing blood vessels so that blood passes through them more easily. It can be used alone or in combination with other drugs used to treat hypertension.

In patients with heart failure, Vasoflex works by relaxing the main blood vessels of the heart, allowing the heart to pump blood more easily. Vasoflex is usually used in heart failure when other drugs are either no longer working or have not worked at all.

In patients with Raynaud's Disease the treatment relaxes blood vessels in the hands, so blood can reach the fingers more easily. This helps to prevent coldness and stiffness.

In patients with enlargement of the prostate gland the treatment is taken to treat poor and/or frequent passing of urine. This is common in patients with enlargement of the prostate gland. The treatment works by relaxing muscle around the bladder and prostate gland so urine is passed more easily.

You should ask your doctor if you are unsure why you have been given Vasoflex.

2 . BEFORE YOU TAKE VASOFLEX

Do not take Vasoflex if you:

- are allergic (hypersensitive) to prazosin, or to any similar drugs (known as quinazoline drugs) or any of the other ingredients. This may have caused itching, reddening of the skin or difficulty in breathing.
- are under 12 years of age.

Take special care with Vasoflex

Medicines are not always suitable for everyone. Your doctor needs to know before you take Vasoflex if any of the following apply to you:

- you have heart failure because of another heart condition, e.g. heart valve disease, or a recent heart attack. If you have heart failure, Vasoflex can gradually become less helpful over several months. If this happens you may notice swelling of your legs or ankles due to retention of fluid. This is called 'oedema'. If you develop oedema or weight gain tell your doctor as your doctor may need to change the dose of Vasoflex or other medicines you are taking.
- you have ever fainted after passing urine.
- you have liver or kidney disease.
- you are undergoing eye surgery because of a cataract (cloudiness of the lens). This is because Vasoflex may cause complications during the surgery which can be managed if your specialist is prepared in advance. Please inform your eye specialist before the operation that you are using or have previously used Vasoflex.

Remember to tell your doctor that you are taking Vasoflex if you have any tests, such as a urine test, as Vasoflex may affect the result.

Taking other medicines

Some medicines can affect the way Vasoflex works. If you are taking any of the following medicines tell your doctor before you start the treatment:

- calcium antagonists, ACE inhibitors or beta-blockers which are usually given to treat angina and/or high blood pressure.
- medicines for erectile dysfunction (impotence).

Some patients who take Vasoflex for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with Vasoflex. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of Vasoflex before you start drugs for erectile dysfunction.

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

Taking Vasoflex with food and drink

Vasoflex can be taken before or after food and drinks.

Pregnancy and Breast-feeding

If you are pregnant, planning to get pregnant or are breast-feeding, tell your doctor before you take Vasoflex.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Vasoflex may cause dizziness, drowsiness or weakness. If you experience these symptoms, do not drive or use any tools or machinery.

3. HOW TO TAKE VASOFLEX

Always take Vasoflex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Vasoflex tablets are to be taken by mouth.

Sometimes Vasoflex can make you feel light-headed or weak particularly when you first take it. This can happen when standing up and can occasionally cause fainting. If the treatment makes you feel light-headed or weak; lie down until you feel better. Get up slowly when you feel better. If you are concerned, tell your doctor. Vasoflex is usually started at the lowest possible dose and gradually increased, depending on how you respond to treatment. Do not change the dose or stop taking the tablets without first checking with your doctor. Make sure you get a new prescription before your tablets run out.

High blood pressure (hypertension)

The recommended starting dose is one 0.5 mg tablet, two or three times a day for 3 to 7 days with the starting dose taken in the evening.

The dose is usually then increased to a 1 mg tablet taken two or three times a day for a further 3 to 7 days. Your doctor may then advise you to gradually increase the dose further (up to a maximum of 20 mg daily) depending on how your blood pressure has responded to treatment.

Heart failure

The recommended starting dose is one 0.5 mg tablet taken two, three or four times a day.

Your doctor may then advise you to increase the dose further (up to a maximum of 20 mg daily) depending on how you have responded to treatment.

Raynaud's disease

The recommended starting dose is one 0.5 mg tablet, twice a day for 3 to 7 days

Your doctor may then advise you to increase the dose further (up to 2 mg twice a day) depending on how you have responded to treatment.

Enlarged prostate

The recommended starting dose is one 0.5 mg tablet, twice a day for 3 to 7 days, with the initial dose taken in the evening. Your doctor may then advise you to increase the dose further (up to 2 mg twice a day) depending on how you have responded to treatment.

If you take more Vasoflex than you should

If you accidentally take too much Vasoflex, contact your doctor immediately or go to your nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Vasoflex left or not.

If you forget to take Vasoflex

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a missed dose.

If you stop taking Vasoflex

Do not stop taking Vasoflex unless your doctor tells you to. Your condition may return if you stop using Vasoflex.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

4. Possible side effects

Vasoflex, like most medicines may cause side effects, but not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe:

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

The following side effects have been reported with Vasoflex:

Common side-effects (occurring in less than 1 in 10 patients):

- feeling faint, fainting or feeling dizzy, particularly on standing-up (see section 3 'How to take Vasoflex')
- headache, drowsiness or weakness
- unpleasant sensation of forceful beating of the heart (palpitations)
- feeling or being sick
- lack of energy, depression or nervousness
- constipation or diarrhoea
- dry mouth, nasal stuffiness or blurred vision
- shortness of breath or rash
- swelling of the feet, ankles or legs
- increase in frequency of passing urine

If any of these cause you problems or if they last for more than one week, you should contact your doctor.

Other side effects that have been reported are listed below:

Uncommon side-effects (occurring in less than 1 in 100 patients)

- stomach discomfort and/or pain
- chest pain or abnormally fast heart beat
- tingling sensation or numbness
- buzzing or ringing in the ear
- nose bleeds, eye pain or red eyes
- difficulty sleeping
- sweating, itching or itchy skin rash
- painful joints
- inability or difficulty in achieving erection of the penis

Rare side-effects (occurring in less than 1 in 1000 patients)

- abnormal blood tests that check for liver function
- pain or infection in the pancreas
- abnormally slow heartbeat
- hallucinations (imagining things which are not really there)
- hair loss
- low blood pressure
- flushing (redness)
- positive ANA (a blood test that checks function of the immune system)
- abnormal breast tissue development, especially in men
- persistent erection of the penis
- an increased tendency to fall asleep if you have a sleep disorder (narcolepsy)
- leaking of urine (incontinence)
- fever or pain
- inflammation of blood vessels

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.

5. HOW TO STORE VASOFLEX

Keep out of the reach and sight of children.

Do not use Vasoflex after the expiry date which is stamped on the pack after EXP. The expiry date refers to the last day of that month.

Store in a cool, dry, place below 30°C.

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.

This leaflet was last revised in 10/2014.