PACKAGE LEAFLET: INFORMATION FOR THE USER

HYPOVASE® 1 mg TABLETS / PRAZOSIN 1 mg TABLETS

(prazosin)

This product is available using either of the above names but will be referred to as Hypovase throughout this leaflet. Please note that the leaflet also contains information about other strength (Hypovase 0.5 mg Tablets).

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, pharmacist or nurse.
- 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. See section 4.

What is in this leaflet:

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

1. WHAT HYPOVASE IS AND WHAT IT IS USED FOR

Hypovase contains the active substance prazosin hydrochloride, which 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) Hypovase 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, Hypovase works by relaxing the main blood vessels of the heart, allowing the heart to pump blood more easily. Hypovase 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 Hypovase, if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HYPOVASE

Do not take Hypovase:

- If you are allergic to prazosin, or to any similar drugs (known as quinazoline drugs) or any of the other ingredients of this medicine (listed in section 6). This may have caused itching, reddening of the skin or difficulty in breathing.
- If you are under 12 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Hypovase. Medicines are not always suitable for everyone. Your doctor needs to know before you take Hypovase 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, Hypovase 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 Hypovase 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 Hypovase 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 Hypovase.
- you have prolonged erection of the penis. If erection persists longer than 4 hours, seek immediate medical help.

Some patients who take Hypovase 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 Hypovase. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of Hypovase before you start drugs for erectile dysfunction.

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

Other medicines and Hypovase

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Some medicines can affect the way Hypovase 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).

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.

Driving and using machines

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

3. HOW TO TAKE HYPOVASE

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

Hypovase tablets are to be taken by mouth.

Hypovase can be taken before or after food and drinks.

The 1mg tablet can be divided into equal doses.

Sometimes Hypovase 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.

Hypovase 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.

In elderly patients, Hypovase will always be started at the lowest possible dose.

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.

Patients with moderate to severe kidney disease and liver disease
The recommended starting dose is one 0.5 mg tablet taken daily. Your doctor will monitor your response to the treatment and any dose increase will be made by your doctor with caution.

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

If you forget to take Hypovase
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 forgotten dose.**

If you stop taking Hypovase
Do not stop taking Hypovase unless your doctor tells you to. Your condition may return if you stop using Hypovase.
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 may cause side effects, although not everybody gets them.

Tell your doctor or call an ambulance immediately if you experience any of the following symptoms of an allergic reaction after taking this medicine. Although they are very rare, the symptoms can be severe and you may need urgent medical attention or hospitalisation:
- 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 Hypovase:

Common: may affect up to 1 in 10 people
- feeling faint, fainting or feeling dizzy, particularly on standing-up (see section 3)
- 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: may affect up to 1 in 100 people
- 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: may affect up to 1 in 1,000 people
- 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

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE HYPOVASE

- **Keep out of the sight and reach of children.**
- Do not store above 30°C.
- Do not use Hypovase after the expiry date which is stamped on the pack after EXP. The expiry date refers to the last day of that month.
- 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
- If the tablets becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hypovase contains
Each tablet contains 1 mg of prazosin (as hydrochloride).
The other ingredients in each tablet are: microcrystalline cellulose, calcium phosphate dibasic anhydrous, corn starch, magnesium stearate and sodium lauryl sulfate.

What Hypovase looks like and contents of the pack
Hypovase is a white and oblong shaped tablet, scored on both sides and engraved "M6" on one side.
Hypovase is available in blister packs containing 60 tablets.

PLGB: 15814/1152 **POM**

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