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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

RANTRAL MR 10 Tablets

Alfuzosin hydrochloride

Contains sugar: lactose anhydrous 77 mg per tablet

Read all of this leaflet carefully before you start taking RANTRAL MR 10

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RANTRAL MR 10 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RANTRAL MR 10 is and what it is used for
2. What you need to know before you take RANTRAL MR 10
3. How to take RANTRAL MR 10
4. Possible side effects



5. How to store RANTRAL MR 10
6. Contents of the pack and other information

1. What RANTRAL MR 10 is and what it is used for

The active substance is alfuzosin hydrochloride. This belongs to a group of medicines called alpha-blockers.

Each RANTRAL MR 10 tablet contains alfuzosin hydrochloride 10 mg (active substance).

RANTRAL MR 10 works by reducing the symptoms (increase in urinary frequency at night and during the day, difficulty in starting the urine flow and dribbling after urination ends and the size and strength of the urine stream may decrease) of **benign prostatic hyperplasia (BPH)**.

In a few patients with benign prostatic hyperplasia, the prostate gland gets so big that it stops the flow of urine completely.

This is called **Acute Urinary Retention (AUR)**.

- This is very painful and you may need a short stay in hospital.
- A thin, flexible tube (catheter) is passed into the bladder. This drains the water and relieves the pain.
- During this time, RANTRAL MR 10 may be used to help the water to flow again. This has only been shown to help in men aged over 65.

2. What you need to know before you take RANTRAL MR 10

Do not take RANTRAL MR 10 tablets if any of the following apply to you:

- If you are hypersensitive (allergic) to alfuzosin or to any of the tablet ingredients (listed in section 6). (Some of the symptoms of an allergic reaction may include skin rash, itching,



difficulty breathing and swelling of the face, lips, tongue and throat).

- You have symptoms like dizziness, lightheadedness, fatigue and sweating on changing posture suddenly (orthostatic hypotension).
- You are taking other α_1 -adrenoceptor blockers (such as tamsulosin, prazosin, terazosin and doxazosin).
- You have liver problems.
- You have severe kidney (s) problems.
- Not indicated for children.

Warnings and precautions

Take special care with RANTRAL MR 10 tablets:

- If you are taking antihypertensive medications, you may develop postural hypotension with or without symptoms (dizziness, light-headedness, fatigue, sweating especially when you get up too quickly from a lying position) within a few hours. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- If you have a heart problem and you experience any worsening of symptoms or occurrence of chest pain after taking any medication consult your doctor immediately.
- In coronary (heart) patients, RANTRAL MR 10 should not be used alone.
- If you are undergoing eye surgery because of cataracts (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used RANTRAL MR 10. This is because RANTRAL MR 10 may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- Tablet should be swallowed whole. Any other mode of administration, such as crunching, crushing, chewing, grinding or pounding to powder should be prohibited. These actions may lead to inappropriate release and absorption of the drug and therefore possible early adverse reactions.



- If you are taking medicines such as such as itraconazole, ketoconazole, protease inhibitors, clarithromycin, telithromycin nefazodone, itraconazole and clarithromycin.
- If you ever get painful erections of the penis, unrelated to sexual activity that will not go away, before or during treatment. If this happens seek medical assistance.

Children and adolescents

RANTRAL MR 10 is not for use in children less than 18 years.

Other medicines and RANTRAL MR 10

Taking other medicines with RANTRAL MR 10:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Care is needed if you are taking following medicines along with **RANTRAL MR 10** Tablets:

- Other alpha₁-adrenoceptor blockers (such as tamsulosin, prazosin, terazosin, doxazosin, etc).
- Antihypertensive medicines (such as atenolol, propranolol, captopril, enalapril, amlodipine, verapamil, diltiazem, etc.)
- General anaesthetics (such as halothane, thiopentone sodium, diazepam, ketamine etc.).
The combination of general anaesthetics and alfuzosin may lead to decrease in blood pressure.
- Medicines for fungal infections (such as ketoconazole and itraconazole) and HIV (ritonavir).



Pregnancy, breastfeeding and fertility

It is not known if RANTRAL MR 10 can harm a human foetus or whether it is excreted in human milk.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines

Care should be taken when driving vehicles or operating machinery as RANTRAL MR 10 may cause dizziness, light-headedness and fatigue.

RANTRAL MR 10 contains lactose

Important information about some of the ingredients of RANTRAL MR 10:

RANTRAL MR 10 contains lactose anhydrous. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take RANTRAL MR 10.

Your medicine also contains small amounts of an inactive ingredient called lactose. If you are lactose intolerant, contact your doctor before taking this medicine.

3. How to take RANTRAL MR 10

Do not share medicines prescribed for you with any other person.

Always take RANTRAL MR 10 exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are unsure. The usual dose is as follows:

For benign prostate hyperplasia:

One RANTRAL MR 10 tablet of daily after meals.



For acute urinary retention:

RANTRAL MR 10 will be given to you by your doctor on the day you have the catheter inserted.

The dose is one RANTRAL MR 10 once a day after meals.

Swallow your tablet whole with plenty of water. You must not break, crush or chew your tablet.

Do not share medicines prescribed for you with others.

To help yourself remember to take your medicine, try to get into the habit of taking it at the same time each day.

Take your tablets as directed and for as long as directed; do not stop them, even if you feel better, as the symptoms may return.

If you have the impression that the effect of RANTRAL MR 10 tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more RANTRAL MR 10 than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available.

Contact the nearest hospital or poison control centre.

Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take RANTRAL MR 10 tablets at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.



4. Possible side effects

RANTRAL MR 10 can have side effects.

Not all side effects reported for RANTRAL MR 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this RANTRAL MR 10, please consult your ~~doctor, pharmacist or other~~ healthcare provider for advice.

If any of the following happens, stop taking RANTRAL MR 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- you get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean that you have an allergic reaction to RANTRAL MR 10.
- you have chest pain (angina).
- you have a painful erection of the penis not related to sexual activity, which will not go away.

These are all very serious side effects. If you have them, you may have had a serious reaction to RANTRAL MR 10. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- feeling dizzy or faint (vertigo)
- headache
- feeling sick (nausea)
- stomach pain (gastralgia)
- weakness or tiredness (asthenia)



Less frequent side effects:

- feeling dizzy, light-headed or faint when you stand or sit up quickly (postural hypotension)
- a fast heart beat (tachycardia) and pounding in the chest and uneven heartbeat (palpitations)
- chest pain
- drowsiness
- diarrhoea
- dry mouth
- rash and itching
- reddening of skin (flushes)
- temporary loss of consciousness (syncope)
- water retention (may cause swollen arms or legs) (oedema)
- general feeling of being unwell (malaise).
- runny nose, itching, sneezing, and stuffy nose (rhinitis)
- Problems with your vision.

Additional side effects (frequency not known) which may occur are:

- Abnormal liver function (liver problem). Signs may include yellowing of your skin or the whites of your eyes.
- Occasionally, problems have risen during cataract surgery in patients taking alfuzosin, such as in RANTRAL MR 10. If you are due to have eye surgery because of cataracts, it is important that you tell the specialist before the operation that you are using or have used RANTRAL MR 10.
- You may get more infections than usual. This could be caused by a decrease in the



number of white blood cells (neutropenia)

- Increased risk of bleeding (including nose bleeds and/or bleeding gums) and bruising. This could be a blood problem called 'thrombocytopenia' which is a reduced number of platelets in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of RANTRAL MR 10.

5. How to store RANTRAL MR 10

Store all medicines out of reach of children.

Store at or below 25 °C in the original container, protected from moisture. Do not store in bathrooms in order to protect from moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. Contents of the pack and other information

What RANTRAL MR 10 contains

The active substance is Alfuzosin hydrochloride

The other ingredients are colloidal anhydrous silica, hypromellose, hydroxypropyl cellulose,



lactose anhydrous, magnesium stearate, povidone and purified talc.

What RANTRAL MR 10 looks like and contents of the pack

White to off-white, uncoated, round, biconvex tablets debossed with 'RY 10' on one side of the tablet.

Ten tablets are packed in clear, transparent, Aclar laminated PVC and aluminium foil blister strips.

Cartons contain 30 or 60 tablets.

Holder of Certificate of Registration

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