

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

In this leaflet:

1. What Ranomax is and what it is used for
2. Before you take Ranomax
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1. WHAT Ranomax IS AND WHAT IT IS USED FOR

The active substance in Ranomax is tamsulosin.

Ranomax is a type of medicine called an alpha1 blocker (α_1 -blocker). It relaxes the muscles in prostate and urethra (the tube running from the bladder). It is used to treat the symptoms associated with prostate enlargement due to a condition called benign prostatic hyperplasia (BPH). These symptoms include difficulty in starting to pass urine (water), frequent trips to the toilet to pass urine, a feeling of not completely emptying your bladder and having to get up in the night to pass urine.

2. BEFORE YOU TAKE Ranomax

Do not take Ranomax :

- if you are allergic (hypersensitive) to tamsulosin hydrochloride or to any of the other ingredients in this product. Hypersensitivity may present as sudden rash (angioedema)
- if you had a previous history of angioedema with tamsulosin
- if you have known history of orthostatic hypotension: low blood pressure (causing dizziness or faintness) when standing up from a sitting or lying position
- if you have a severe liver condition.

Take special care with Ranomax

- If you suffer from severe kidney problems (creatinine clearance less than 10 ml/min), with this condition discuss this with your doctor or pharmacist before taking Ranomax.
- As with other medicines of this type (α_1 blockers), Ranomax can cause a lowering of blood pressure in some people. This can occasionally cause fainting.
- If you start to feel weak or dizzy, make sure you sit, or lie down, straight away until the symptoms have disappeared. You should not drive or operate machinery if you feel faint, dizzy and drowsy or have blurred vision until the symptoms have passed.
- If you are due to undergo a cataract operation (for cloudiness of the lens of the eye). Inform your eye specialist that you are using (or have recently used) Ranomax before you have your operation see section 4). Your doctor will advise you whether to continue taking this medicine until you have your operation.

Before starting treatment with Ranomax 400 micrograms Prolonged release capsules, you should be examined by your doctor to confirm the diagnosis and exclude other conditions which may produce similar symptoms but require different treatment.

Taking other medicines

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

It is particularly important to mention any blood pressure medicines, particularly other medicines similar to this (alpha blockers) as their effect on your body may be increased with tamsulosin. This can cause an unwanted fall in blood pressure.

Pregnancy and breast-feeding

Not applicable as this is a product for men only.

Driving and using machines

Ranomax can occasionally cause faintness or symptoms such as dizziness, drowsiness or blurred vision. Do not drive or operate machinery if you have any of these symptoms.

Important information about some of the ingredients of Ranomax

Allergic reactions may occur due to the colouring agents used in this product: sunset yellow (E110), azorubine (E122), and ponceau 4R (E124).

3. HOW TO TAKE Ranomax

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

To be taken by mouth.

Ranomax should be taken according to your doctor's instructions. Ask your doctor or pharmacist if you are unsure. The usual dose is one capsule, a day and it should be taken after breakfast or after the first meal of each day.

The capsule should be swallowed whole, with a drink of water, and it should NOT be crunched or chewed.

It is advisable to take this medicine while standing up or sitting down and NOT while lying down.

If you take more Ranomax than you should: If you have taken too many capsules, tell your doctor straight away. Because of the way the medicine works, taking too much could affect your blood pressure.

If you forget to take Ranomax: You may take your capsule later the same day after food if you have forgotten to take it earlier. If you have missed a day, just continue to take your daily capsule from the next day. Do NOT take two capsules together to make-up for the forgotten dose.

If you stop taking Ranomax: If the treatment is stopped earlier than recommended, then the original symptoms may return. For this rea-

son, use Ranomax for the duration of your treatment, as recommended by your doctor even though your symptoms may have disappeared.

If you have any questions about taking this medicine, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ranomax may cause side-effects, although not everybody gets them.

Common (less than 1 in 10, more than 1 in 100 (1-10%)):

Dizziness, particularly when going to sit or stand up.

Uncommon (more than 1 in 1000, less than 1 in 100 (0.1-1%)):

Headache, palpitations (the heart beats more rapidly than normal and it is also noticeable), reduced blood pressure e.g. when getting up quickly from a seating or lying position sometimes associated with dizziness; runny or blocked nose (rhinitis), diarrhoea, feeling sick and vomiting, constipation, weakness (asthenia), rashes, itching and hives (urticaria), abnormal ejaculation. The latter means that semen does not leave the body via the urethra, but instead goes into the bladder. This phenomenon is harmless.

Rare (more than 1 in 10,000, less than 1 in 1000 (0.01-0.1%)):

Faintness and sudden local swelling of the soft tissues of the body (e.g. the throat or tongue) difficult breathing and / or itching and rash, often as an allergic reaction (angioedema).

Very rare (less than 1 in 10,000 (<0.01%)):

Priapism (painful prolonged unwanted erection for which immediate medical treatment is required).

Consult your doctor immediately if these occur.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you are undergoing a cataract operation (for cloudiness of the lens in the eye) and are taking, or have recently taken, Ranomax it is important to tell your doctor about this before you have your operation. Your doctor can take steps to avoid a problem with the eye, called "floppy iris syndrome", during the operation.

5. HOW TO STORE Ranomax

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions

Do not use Ranomax after the expiry date which is stated in label. The expiry date refers to the latest 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.

6. FURTHER INFORMATION

What Ranomax contains

- The active substance is tamsulosin hydrochloride. One prolonged release capsule contains 400 micrograms of tamsulosin hydrochloride.
- The other ingredients are:

Capsule contents: cellulose microcrystalline PH101, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion, sodium hydroxide, triacetin, titanium dioxide (E171), purified talc.

Capsule body: gelatine, sunset yellow, ponceau 4R (E124), quinoline yellow (E104), brilliant blue (E133), titanium dioxide (E171).

Cap composition: gelatine, yellow iron oxide (E172), brilliant blue (E133), azorubine (E122), titanium dioxide (E171).

Printing ink: activated charcoal, shellac.

What Ranomax looks like and contents of the pack

Ranomax 400 micrograms prolonged release capsules comprise of Brown cap/Orange body of size "2" imprinted with 'R' on cap and "TSN400" on body in black edible ink containing white to off-white granules.

Packs of 1, 2, 4, 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 98 or 100 prolonged release capsules.

Marketing Authorisation Holder and Manufacturer

MARKETING AUTHORISATION HOLDER: VIOGEN Pharmaceuticals, El. Venizelou Av.309, 176 74 Kallithea, Athens, Greece.

MANUFACTURER: Ranbaxy Ireland Limited, Spafield, Cork Road, Cashel, Co – Tipperary
Republic of Ireland.

For any information about this medicinal product, please contact the Marketing Authorisation Holder.

This leaflet was last approved in {07/10}.

General classification for supply

Subject to medical prescription.