

Regitine, 10 mg/ml, solution for injection

phentolamine mesylate

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. What Regitine is and what it is used for
2. What you need to know before you use Regitine
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1. WHAT REGITINE IS AND WHAT IT IS USED FOR

The active substance in Regitine is phentolamine. It belongs to a group of medicines called alpha blockers. These medicines lower high blood pressure by relaxing blood vessels.

Regitine can be used in the following cases:

- For the treatment of high blood pressure caused by a tumour of certain cells in the adrenal medulla (pheochromocytoma) before and during the surgery.
- As a test to diagnose pheochromocytoma, if other tests are not available.
- Prevention of damage to your skin during an intravenous injection of noradrenaline if this substance has accidentally entered the tissue outside the blood vessels.

Ask your doctor if you are not sure why Regitine is going to be used for you.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE REGITINE

Do not take Regitine:

- if you are allergic to any of the ingredients of this medicine (listed in section 6).
- if you are hypersensitive to sulphite.
- if you have low blood pressure.
- if you are having a heart attack or if you have had a heart attack in the past.
- if your heart does not function properly and if you have chest tightness or any other signs of disease of the blood vessels around the heart.

Warnings and precautions

Talk to your doctor or pharmacist before using Regitine:

- if you have fast or irregular heartbeats.
- if you have heartburn, abdominal pain, nausea or vomiting.
- if you have darker coloured stools or blood in your stools.
- if you have kidney impairment.

Children and adolescents

Regitine can be used in children and adolescents.

Other medicines and Regitine

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This applies especially to

other blood-pressure-lowering medicines and medicines for the treatment of certain mental and emotional disorders.

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 for advice before taking this medicine. Your doctor will inform you about the benefits and risks and decide whether Regitine can be used for you.

Also talk to your doctor if you want to breast-feed. Regitine is not advised for use in breast-feeding women.

Driving and using machines

Regitine may cause dizziness or other side effects. Do not drive or use machines if this happens to you. If so, contact your doctor.

Regitine contains sodium metabisulfite.

Regitine contains less than 23 mg sodium per dose, i.e. is essentially "sodium free". Regitine contains sodium metabisulfite. In rare cases, sodium metabisulfite can cause severe hypersensitivity reactions and shortness of breath due to spasm of the muscles of the airways (bronchospasm).

3. HOW TO TAKE REGITINE

Your doctor will determine the dose and administer the medicine.

Duration of the treatment

Your doctor will decide the duration of the treatment.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (in more than 1 in 10 patients):

- fast heart rate (tachycardia)
- low blood pressure when sitting or standing up (orthostatic hypotension)

Common side effects (in fewer than 1 in 10 patients):

- dizziness
- sudden or prolonged periods of low blood pressure (may lead to a heart attack or stroke)
- flushing
- blocked nose
- nausea
- vomiting
- diarrhoea
- general body weakness/feeling weak (asthenia)

Uncommon side effects (in fewer than 1 in 100 patients):

- tight, painful feeling in the chest (angina)
- abnormal heart rhythm (arrhythmia)

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 website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE REGITINE

Store in the original package.
Store in a refrigerator (2°– 8°C) Do not freeze.
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box after "Exp". This lists a month and a year. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Regitine contains

The active substance is phentolamine mesylate. Each ampoule of 1 ml contains 10 mg phentolamine mesylate. This is equivalent to a total of 7.45 mg/ml phentolamine.

The other ingredients are sodium metabisulfite, glucose and water for injections.

What Regitine looks like and contents of the pack

Each pack of Regitine contains 5 ampoules of 1 ml.

Marketing Authorisation Holder and Manufacturer

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Regitine is registered in the Netherlands under RVG 01635.

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