

# REGITINE<sup>®</sup>

## 10mg/1mL Injection

### phentolamine mesilate

## What is in this leaflet

This leaflet answers some common questions about Regitine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Regitine against the benefits they expect it will have for you.

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

## What Regitine is used for

Regitine is an agent used to lower episodes of high blood pressure in patients suffering from phaeochromocytoma (a condition with excess production of hormones like adrenaline from tumors of the adrenal gland), when these episodes occur during preparation for an operation or during the surgery for this tumour. It is also used to diagnose this disease if other more specific tests are not available.

Furthermore, Regitine is used to prevent a damage of your skin if during an intravenous injection of noradrenaline this compound has passed accidentally out from your veins into the surrounding tissue.

**Ask your doctor if you have any questions about why Regitine has been prescribed for you.**

Your doctor may have prescribed it for another purpose.

Regitine is only available with a doctor's prescription. It is not habit-forming.

## Before you are given Regitine

### ***When you must not be given it***

**You must not be given Regitine if you have ever had an allergic reaction to:**

- phentolamine, the active ingredient in Regitine
- sodium metabisulphite, an ingredient in Regitine, or any other sulphites in medicines or foods
- any of the other ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**You must not be given Regitine if you have any of the following medical conditions:**

- low blood pressure
- a heart attack now or at any time in the past
- heart disease

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

### **How Regitine works**

Phentolamine decreases blood pressure by dilating blood vessels.

### ***Before you are given it***

**Tell your doctor if you have any of the following medical conditions:**

- fast or irregular heart beat
- heart burn, abdominal pain, nausea, vomiting or dark coloured stools or blood in your stools
- kidney problem
- asthma
- high blood pressure

Your doctor may want to take special precautions if you have any of the above conditions.

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

Your doctor will want to know if you are prone to allergies.

**If you have not told your doctor about any of these things, tell him/her before you are given Regitine.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and Regitine may interfere with each other. These include:

- other medicines used to treat high blood pressure
- antipsychotic medicines used to treat some mental disorders
- medicines to help you sleep or calm you down
- pain relievers
- dopamine, a medicine used to treat shock

These medicines may be affected by Regitine or they may affect how well it works. Your doctor and pharmacist have more information.

### **Older people (65 years and above)**

Consult your doctor who will guide whether you should be given Regitine or not.

### **Children and adolescents**

Regitine can be used in children and adolescents.

### **Pregnancy and breast-feeding**

Tell your doctor if you are pregnant or are planning to become pregnant or if you are breast-feeding. Your doctor will tell you about the benefits and risks involved and decide whether you should be given Regitine.

## **How Regitine is given**

Use during surgery: for an adult, 2 to 5 mg of Regitine is injected intravenously (into a vein) or injected in a muscle or under the skin and repeated if necessary, depending on the blood pressure response. For a child, the lowest effective dose is given.

Use as a diagnostic test:

- other medicines you may be taking, including medicines for treating high blood pressure, are usually ceased for at least 24 hours before the test is done. This allows your blood pressure to return to its usual level.
- during the test you will lie down, preferably in a quiet, darkened room, until your blood pressure is constant
- a single injection of 5 mg of Regitine will be given intravenously (into a vein) or intramuscularly (into a muscle). The dose for a child is 1 mg into a vein or 3 mg into a muscle.
- you will remain lying flat while your blood pressure is taken every few minutes for at least 30 minutes.
- a fall in blood pressure of more than a certain amount indicates that there is an adrenal tumour.

## **Side effects**

**Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Regitine.**

As with all medicines, patient receiving Regitine may experience side effects, although not everyone gets them.

**Tell your doctor or nurse about any of the following side effects as soon as possible:**

- low blood pressure with dizziness, lightheadedness, and weakness (short or prolonged episodes of low blood pressure may cause heart attack or stroke)
- fast or irregular heart beat
- chest pain
- nausea and vomiting
- diarrhoea
- flushing
- nasal stuffiness

**Tell your doctor if you notice any other unexpected effects.**

## **Product description**

### ***What it looks like***

Regitine is available in a glass ampoule containing a colourless to faintly yellowish clear liquid; in packs of 5 ampoules.

### ***Ingredients***

Each ampoule of Regitine contains 10 mg of phentolamine (as mesilate). The ampoule also contains:

- sodium metabisulphite
- glucose-anhydrous
- water for injections.

### ***Sponsor***

Regitine is supplied in New Zealand by:

Novartis New Zealand Limited

Private Bag 65904

Mairangi Bay

Auckland

Building G, 5 Orbit Drive

Rosedale

Auckland 0632

Telephone 0800 652 422

### ***Date of preparation***

This leaflet was prepared on 14 October 2011 based on the current data sheet for this product.

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