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.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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 with the medicine. You may need to read it again.

What Regitine is used for

Regitine is an injection that lowers episodes of high blood pressure in patients suffering from phaeochromocytoma, a rare tumour of the adrenal gland, when these episodes occur during preparation for an operation or during the surgical removal of this tumour.

Often during the surgery, the tumour produces chemicals that cause a sudden rise in blood pressure. Regitine can help to prevent or reverse this rise in blood pressure.

Regitine can also be used as a diagnostic test to find out if you have an adrenal tumour, when other tests are not available.

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.

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Before you are given it

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

• inflammation of the stomach (gastritis) or a stomach ulcer
• asthma
• fast or irregular heart beat
• 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 pregnant or breast-feeding.

There is not enough information to recommend the use of Regitine during pregnancy or while breast-feeding. Your doctor can advise you about the risks and benefits involved.

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.

• 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
• angina or other heart problems
• kidney problems

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.
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
- adrenaline, isoprenaline, i.e. nonselective beta-agonist, medicines used for cardiac disorders, or during surgery

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

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**How Regitine is given**

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Regitine is usually given in hospital, either during surgery or as a diagnostic test. It will be given to you as needed under the supervision of your doctor.

Regitine is given by injection directly either into a vein (intravenously) or into a muscle (intramuscularly).

**For diagnostic use:**

1. Before the diagnostic test is done, your doctor may ask you to stop taking other medication for at least 24 hours prior to the test, including any medicines for treating high blood pressure. This allows your blood pressure to return to its usual level.

2. Follow all instructions given to you by your doctor or nurse.

3. During the diagnostic test, you will lie down, preferably in a quiet darkened room, until your blood pressure is constant.

4. A single injection of Regitine will usually be given.

5. You will remain lying flat while your blood pressure is taken every few minutes for at least 30 minutes.

6. A fall in blood pressure of more than a certain amount after you have been given Regitine suggests that there is an adrenal tumour present.

**How much is given**

The usual dose given depends on what condition Regitine is being used for. Your doctor will know this.

**During surgery:**

- Adults:
  - 2 mg to 5 mg of Regitine is injected into a vein and repeated if necessary, depending on the blood pressure response

- Children:
  - the lowest effective dose is given into a vein (intravenously).

**During diagnostic tests:**

- Adults:
  - a 5 mg Regitine injection will be given either into a vein or muscle.

- Children:
  - either a 1 mg injection into a vein or a 3 mg injection into a muscle will be given

**How often it is given**

Usually you will only be given one dose of Regitine. The treatment may be repeated if necessary.

Your doctor will decide how many treatments you need and how often you should receive them.

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**If you have too much (overdose)**

As Regitine is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

If you think that you may have been given too much Regitine, immediately alert your doctor or the nurse.

**Side effects**

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing
- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- chest pain
- dizziness or light headedness, especially when standing up suddenly
- weakness
- headache
- nausea (feeling sick) or vomiting
- diarrhoea
- pain in the stomach or abdomen
- flushing of the face
- congested (blocked) nose

The above side effects may require medical attention.
If you are driving, operating machinery or doing jobs that require you to be alert shortly after having the Regitine test, be careful until you know how this medicine has affected you.

This medicine may cause dizziness or light headedness in some people.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

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**Ingredients**

**Active Ingredient**
Regitine contains 10 mg of phentolamine mesylate

**Inactive ingredients**
- sodium metabisulphite (E 223)
- glucose-anhydrous
- water for injections

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**Sponsor**

Regitine is supplied in Australia by:
NOVARTIS Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1 800 671 203

Web site: www.novartis.com.au

® = Registered trademark

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**Date of preparation**

This leaflet was prepared in October 2011.

Australian Registration Number.
Regitine Ampoule AUST R 11051

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**Product description**

**What it looks like**

Regitine is available in a glass ampoule containing a colourless to faintly yellowish clear liquid. Each carton contains 5 ampoules.