

Apresoline[®]

hydralazine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Apresoline.

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. 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 having Apresoline against the benefits they expect it will provide.

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

Keep this leaflet.

You may need to read it again.

What Apresoline is used for

Apresoline is an injection that is used when your blood pressure is very high and needs to be brought down quickly.

Apresoline belongs to a group of medicines called vasodilators. It acts by relaxing and widening (dilating) the walls of blood vessels. This action helps to reduce blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Apresoline is only available with a doctor's prescription. It is not addictive.

Before you are given Apresoline

When you must not have it

You must not have Apresoline if you have ever had an allergic reaction to hydralazine, the active ingredient in Apresoline.

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 have Apresoline if you have any of these medical conditions:

- systemic lupus erythematosus (SLE) or a related disease
- recent heart attack or other severe heart problems
- an overactive thyroid (called thyrotoxicosis)

- swelling and weakening of part of a large blood vessel (called an aneurysm)

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

Apresoline must not be given to children.

There is not enough information to recommend its use in children.

Before you have it

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

- chest pain (angina) or other heart problems even if not severe
- kidney problems
- liver problems
- recent stroke or other blood vessel disease

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

Tell your doctor if you are pregnant or breast-feeding. Ask your doctor about the risks and benefits involved.

Apresoline may affect your developing baby if you have it while you are pregnant, although it is often used near the end of pregnancy to lower very high blood pressure. The active ingredient of Apresoline passes into the breast milk and could affect your baby if you breast-feed.

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 have Apresoline.

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 Apresoline may interfere with each other. These include:

- some other medicines used to treat high blood pressure
- some medicines used to treat heart problems
- diuretics (fluid tablets), which are medicines used to reduce water retention and high blood pressure
- some medicines used to treat depression such as MAOIs and tricyclic antidepressants
- selegiline, a medicine used to treat Parkinson's disease
- some medicines used to treat mental disorders

These medicines may be affected by Apresoline or they may affect how well it works. You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are having Apresoline.

How Apresoline is given

How much you need

Your doctor will decide how much you need and how often the injections will be given. The first dose of Apresoline is usually 5 to 10 mg. After 20 or 30 minutes, another dose can be given, if necessary, to bring your blood pressure down.

How it is given

Apresoline is usually given in hospital. The dry powder in the ampoule is dissolved in sterile water just before use. It can be given by slow injection directly from the syringe into a vein or by infusion (drip) over a longer period.

How long your treatment will last

Apresoline is only used over a short period to quickly bring down very high blood pressure. After that, you may have to take blood pressure tablets to help keep your blood pressure down.

If you have too much (overdose)

If you think that you may have been given too much Apresoline, immediately alert your doctor or the nursing staff in the hospital.

Symptoms such as a fast or irregular heartbeat, dizziness or faintness, nausea (feeling sick), vomiting or sweating, may mean your blood pressure has fallen too far.

While you are being given Apresoline

Things you must do

Before having any surgery or emergency treatment, tell the doctor or anaesthetist in charge that you are being treated with Apresoline.

This medicine may interfere with some of the medicines used during surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Apresoline.

Tell any other doctor, dentist or pharmacist who treats you that you are being treated with Apresoline.

Things to be careful of

If you are driving, operating machinery or doing jobs that require you to be alert shortly after having Apresoline, be careful until you know how this medicine has affected you.

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

Be careful if you are drinking alcohol shortly after having Apresoline.

The combination could make your blood pressure fall further than usual, causing you to feel dizzy or light headed.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Apresoline.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following side effects and they worry you:

- dizziness or light headedness, especially when standing up suddenly
- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- feeling anxious or agitated
- headache
- nausea (feeling sick) or vomiting
- feeling generally unwell, loss of appetite or weight loss
- diarrhoea

- flushing of the face
- congested (blocked) nose
- red, swollen or teary eyes
- pain or swelling of joints, muscles or nerves
- shaking or tremors
- numbness or tingling in hands or feet

Tell your doctor immediately 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
- constant "flu-like" symptoms such as fever, sore throat, swollen glands, tiredness, lack of energy
- unusual bruising or bleeding under the skin
- yellow colour to skin or eyes
- sudden decrease in the amount of urine or pain when passing urine; blood in the urine
- swelling of feet or legs due to extra fluid
- chest pain
- pain in the stomach or abdomen

- depression or hallucinations (seeing things that aren't there)

The above side effects could be serious. You may need urgent medical attention.

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.

After being given Apresoline

Storage

It is unlikely that you will have to store your ampoules at home. If you do need to store them, you should:

- keep the ampoules in the cardboard carton until it is time to use them
- store them in a cool dry place
- do not store Apresoline or any other medicine in the bathroom or near a sink
- do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines. Apresoline will keep well if it is cool and dry.

Keep the ampoules where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor stops your treatment or the expiry date on the medicine has passed, ask your pharmacist what to do with any ampoules you have left over.

Product description

What it looks like

Apresoline comes in a clear glass ampoule containing the active ingredient, hydralazine hydrochloride, in a dry powder form; 5 ampoules in a cardboard carton.

Ingredients

Each ampoule of Apresoline contains 20 mg of hydralazine hydrochloride. The ampoule contains no other ingredients.

Sponsor

Apresoline is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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Telephone: 1 800 671 203

This leaflet was prepared in June 2007.

Australian Registration Number.

Apresoline ampoule: AUST R 43190