Apresoline

Hydralazine hydrochloride Injection 20 mg

What is in this leaflet

Please read leaflet carefully before you start taking Apresoline

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Apresoline against the benefits it can provide.

If you have any concerns about Apresoline, ask your doctor or pharmacist. Keep this leaflet with the medicine. 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 Apresoline has been prescribed for you.

Your doctor may have prescribed Apresoline for another purpose.

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

Before you take Apresoline

When you must not take Apresoline

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:

- idiopathic systemic lupus erythematosus (SLE), a disease affecting the skin, joints and kidneys 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)
- mvocardial insufficiency due to mechanical obstruction
- porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin. Porphyrins are excreted in the urine, which becomes

dark; other symptoms include mental disturbances and extreme sensitivity of the skin to light.)

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 start to take the medicine

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 but reports available so far do not suggest an adverse effect on the infant.

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 (e.g., minoxidil, verapamil, enalapril, chlorthalidone)
- anesthetics (a substance that induces insensitivity to pain., e.g., painkillers)
- major tranquillisers (a medicinal drug taken to reduce tension or anxiety, e.g., olanzapine, haloperidol, promethazine).
- nitrates (medications used for treating or preventing chest pain (angina) caused by heart disease) or medicines exerting central depressant actions (including alcohol, pregabalin, hydrocodone, codeine).
- taking Apresoline shortly before or after proglycem (diazoxide) may give rise to

marked decrease in blood pressure.

- some medicines used to treat heart problems (inspra, aldoctone, epinephrine, verapamil)
- beta-blockers (sectral, tenormin, lopressor)
- diuretics (fluid tablets), which are medicines used to reduce water retention and high blood pressure (chlorthalidone)
- some medicines used to treat depression such as MAOIs (azilect, marplan) and tricyclic antidepressants (elavil, tofranil)
- selegiline, a medicine used to treat Parkinson's disease
- some medicines used to treat mental disorders (prozac, effexor, brintellix)

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 to use the Medicine

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.

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:

- allergic reaction
- dizziness or light headedness, especially when standing up suddenly
- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- · feeling anxious or agitated
- shortness of breath, sharp chest pains which is worse when breathing in
- 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
- depression
- hallucinations (an experience involving the apparent perception of something not present.)
- increase secretion of tears
- discharge with itching of the eyes and crusty eyelidsbulging or protruding eyeball or eyeballs
- fever
- yellowing of the skin and/or eyes, also called jaundice

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.

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. Further signs and symptoms include loss of awareness, headache, tremors, fits, the production of abnormally small amounts of urine and low body temperature.

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 and decrease in blood pressure 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.

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.

Other ingredients

Apresoline does not contain any other ingredients. It is dissolved in Water for Injections before it is used.

If you want to know more

Talk to you doctor or pharmacist. They will be able to answer your questions.

Distributor

Apresoline is supplied in New Zealand by: AFT Pharmaceuticals Ltd. PO Box 33.203 Takapuna AUCKLAND

Apresoline is supplied in Singapore by: A. Menarini Singapore Pte Ltd 30 Pasir Panjang Road, #08-32 Mapletree Business City Singapore 117440

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