

Apresoline®

hydralazine hydrochloride

Consumer Medicine Information

What is in this CMI

This CMI 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 giving you Apresoline against the benefits they expect it will have for you.

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

Keep this information.

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 is used to reduce very high blood pressure especially during late pregnancy.

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 and increase blood and oxygen supply to the heart, brain, spleen and kidneys.

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 be given Apresoline if you have ever had an allergic reaction to:

- hydralazine, the active ingredient in Apresoline
- dihydralazine
- any of the 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 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, e.g. due to inflammation around the heart, narrowing of blood vessels or heart valves, or related to increased demand on the heart in diseases such as thyrotoxicosis (overactive thyroid gland)
- right heart failure due to pulmonary hypertension (high pressure in blood vessels supplying the lungs)

- swelling and weakening of part of a large blood vessel (called an aneurysm)
- a rare blood pigment disorder known as porphyria

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 allergies to any other medicines, foods, preservatives or dyes.

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

- chest pain (angina) or other heart problems whether or not severe
- previous heart attack
- problems with blood flow to the brain, e.g. stroke, mini-stroke or transient ischaemic attack (TIA)
- kidney problems
- liver problems

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

Tell your doctor if you are pregnant or plan to become pregnant.

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. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

The active ingredient of Apresoline passes into breast milk and could affect your baby if you breastfeed.

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:

- other medicines used to treat high blood pressure, such as vasodilators (e.g. diazoxide), calcium antagonists, ACE inhibitors or beta-blockers (e.g. propranolol, metoprolol)
- diuretics (fluid tablets), medicines used to reduce water retention and treat high blood pressure
- some medicines used to treat heart problems
- monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's Disease
- some other medicines used to treat depression, such as tricyclic antidepressants
- central depressants, sometimes referred to as sedatives and tranquillisers (medicines to help you sleep, reduce anxiety, induce anaesthesia or treat psychosis)
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation
- adrenaline (epinephrine), used to raise blood pressure, e.g. due to a heart attack or serious allergic reaction
- oestrogens, e.g. used in the contraceptive pill and in

hormone replacement therapy (HRT)

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 receiving 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. 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 bring down very high blood pressure quickly. 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, headache, chest pain,

tremors, fits 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 drinking alcohol after being treated with 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 being treated with 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
- 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 skin
- congested (blocked) nose
- red, swollen or teary eyes
- 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 or wheezing
- painful or swollen joints, particularly if accompanied by skin rash, fever, persistent tiredness or chest pain
- difficult or painful 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
- 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.

Some side effects can only be found if your doctor does tests on your blood or urine.

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

The pharmacy is responsible for the appropriate storage of Apresoline.

The ampoules should be stored protected from light, where the temperature stays below 25°C.

Disposal

If you have any unused Apresoline, return it to the pharmacy.

The pharmacy will dispose of any unused Apresoline.

Product description

What it looks like

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

Ingredients

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

Sponsor

Amdipharm Mercury (Australia) Pty Ltd
Level 9, 76 Berry Street
North Sydney, NSW 2060

Australian Registration Number:
AUST R 43190

Date of preparation:

This leaflet was revised on 3 April 2017.

Amdipharm Mercury (Australia) Pty Ltd is licensed to use the trademark Apresoline.