

Package leaflet: Information for patient

Apresoline Ampoules 20mg Powder for concentrate for solution for injection or infusion Hydralazine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Apresoline Ampoules 20mg Powder for concentrate for solution for injection or infusion and will be called Apresoline Ampoules 20 mg throughout the rest of this leaflet.

What is in this leaflet

- 1.What Apresoline Ampoules 20 mg are and what they are used for
- 2.What you need to know before you use Apresoline Ampoules 20 mg
- 3.How to use Apresoline Ampoules 20 mg
- 4.Possible side effects
- 5.How to store Apresoline Ampoules 20 mg
- 6.Contents of the pack and other information

1.What Apresoline Ampoules 20 mg are and what they are used for

Apresoline Ampoules 20 mg contain 20mg hydralazine hydrochloride. Hydralazine is an anti-hypertensive – it is used to treat high blood pressure. It works by relaxing blood vessels and increasing the supply of blood and oxygen to the heart.

Apresoline is used to treat very high blood pressure, particularly when this condition occurs in pregnancy (pre-eclampsia and toxemia of pregnancy) or in patients with kidney disease.

2.What you need to know before you use Apresoline Ampoules 20 mg

Do not use Apresoline Ampoules 20mg if :

- you are allergic to hydralazine or any of the other ingredients of this medicine (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);

- you suffer from severe tachycardia or right sided heart failure due to increased pressure in the blood vessels of the lungs (cor pulmonale);
- you suffer from heart failure (Myocardial insufficiency) due to mechanical obstruction (e.g. aortic or mitral stenosis or constrictive pericarditis).
- you have or have ever had a condition called Systemic Lupus Erythematosus (SLE), an autoimmune condition which causes joint pain, skin rashes and fever;
- you have diformity of aorta (Dissecting aortic aneurysm)

Warning and precautions

Talk to your doctor or pharmacist or nurse before using Apresoline Ampoules 20mg

If you ever had a rash or other possible allergic reaction whilst taking hydralazine

If you suffer from any serious heart or blood vessel disease

If you are a slow acetylator

If you suffer from systemic lupus erythematosus (SLE)

If you are experiencing fever, loss of appetite, weight loss, tiredness, general body pain, coughing up of blood, swelling of feet and ankles, blood in urine while on treatment with Hydralazine which could be due to a condition known as systemic vasculitis leading to a rare medical syndrome involving bleeding in the lungs and kidney damage (Pulmonary renal syndrome) (See section 4)

If you had a heart attack or stroke within the past three months

If you are planning to undergo surgery

Other warning:

- Whilst you are taking Apresoline, your doctor will want to check your progress at regular intervals.

Other medicines and Apresoline Ampoules 20 mg :

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. It is especially important that you tell your doctor if you are taking:

- Medicines for the treatment of high blood pressure, such as diuretics (water tablets, eg bendroflumethiazide or furosemide).
- Alcohol
- Anesthetic medications
- Tricyclic antidepressants (eg amitriptyline)
- Tranquilizers or central nervous system depressants
- Monoamine oxidase (MAO) inhibitors (eg tranylcypromine, phenelzine)
- Diazoxide
- Beta blockers (eg atenolol, propranolol)

Apresoline Ampoules 20 mg with food and drink and alcohol

It is advisable not to drink alcohol whilst taking apresoline as it may affect you more than usual.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

Driving and using machines

If you feel dizzy after treatment with Apresoline, do not drive or work with machinery until these effects have worn off.

3. How to use Apresoline Ampoules 20 mg

Always use this medicine exactly as your doctor or pharmacist has told you.. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 5 to 10 mg repeated as necessary. Your doctor will decide when and how to treat you with Apresoline ampoules. The powder in the ampoules will be dissolved and usually drawn into a syringe and injected slowly into your vein (intravenous injection); it may be further diluted and injected very slowly into a vein (intravenous infusion). Your blood pressure will be taken throughout and the dose adjusted to ensure a gradual fall in blood pressure to normal levels.

Use in children

- Apresoline is not suitable for children.

If you use more Apresoline Ampoules 20 mg than you should

As the injection will be administered by a doctor, it is unlikely that you will be given more than is necessary. Should an overdose occur, the doctor will treat any symptoms that follow.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicine and seek immediate medical advice if you notice the following:

- SLE-type syndrome, which can cause symptoms such as joint pain, fever, change in blood count and skin rash.
- Allergic reactions including itching, skin rash, inflammation of the walls of small blood vessels and difficulty in breathing.
- Yellowing of the skin and whites of the eyes, which may indicate problems with the liver such as jaundice and hepatitis.

Other side effects may include:

Very common: may affect more than 1 in 10 people

- Headache
- An unusually fast heart beat (tachycardia)
- Abnormal heart beat (palpitations)

Common: may affect up to 1 in 10 people

- Flushing
- Low blood pressure
- Chest pain,
- Stomach pain,
- Diarrhoea,
- Feeling sick
- Vomiting
- Pain in joint (arthralgia)
- Joint swelling
- Pain in muscle (myalgia)

Uncommon: may affect up to 1 in 100 people

- A decrease in the amount of red blood cells (RBCs) or hemoglobin in the blood (Anemia)
- A reduction in the number of white cells in the blood (leucopenia)
- Abnormally low count of neutrophils, a type of white blood cell that helps fight off infections (Neutropenia)
- Deficiency of platelets in the blood (thrombocytopenia) with or without rash
- Agitation
- Loss of appetite
- Anxiety
- Lightheadedness
- Watering of the eyes
- Sore itchy eyes
- Swelling of feet or leg
- Heart failure
- Shortness of breath
- Chest pain while breathing
- Nasal congestion
- The presence of abnormal quantities of protein in the urine (Proteinuria)
- Increased creatinine (Blood component)
- Presence of blood in urine (hematuria) sometimes in association with kidney inflammation
- Fever
- Decreased weight
- Feeling tired.

Very rare: may affect up to 1 in 10,000 people

- Abnormal breakdown of red blood cells (RBCs)
- An increase in the number of white cells in the blood
- A disease affecting the lymph nodes (lymphadenopathy)
- Deficiency of all three cellular components of the blood (red cells, white cells, and platelets)
- Abnormal enlargement of the spleen
- A deficiency of granulocytes in the blood
- Depression
- Delusion (Hallucination)
- Disease affecting nerves which may impair sensation (peripheral neuritis/polyneuritis/paraesthesia) and tremor
- Bulging of eye
- Episodes of high blood pressure
- Paralysis of the intestine
- Kidney failure
- Inability to urinate

Not known: frequency cannot be estimated from the available data

- inflammation of blood vessels including Pulmonary-renal syndrome is a rare medical syndrome involving bleeding in the lungs and kidney damage

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5.How to store Apresoline Ampoules 20 mg

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original container in order to protect from light.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment
Single use only. The product should be used immediately after reconstitution and not stored. It should not be used if deteriorated.

6. Contents of the pack and other information

What Apresoline Ampoules 20 mg contain:

Apresoline ampoules contain 20mg hydralazine hydrochloride.

What Apresoline Ampoules 20 mg look like and contents of the pack

Apresoline ampoules come in packs of 5.

Pharmaceutical form: powder for concentrate for solution for injection or infusion.

The appearance of the product after reconstitution is a clear, colourless to slightly yellowish solution.

Marketing Authorisation Holder and Manufacturer

Product Authorisation Holder:

Amdipharm Limited,
Temple Chambers,
3 Burlington Road,
Dublin 4, Ireland

Manufacturer:

Novartis Pharmaceuticals UK Limited,
Wimblehurst Road,
Horsham,
West Sussex,
RH12 5AB,
England

This leaflet was last revised in December 2015.