Hydralazine 20mg Powder for Concentrate for Solution for Injection/Infusion

Hydralazine hydrochloride

Read all of this leaflet carefully before you start taking this medicine
- Keep this leaflet. You may need to read it again.
- If you have any further questions ask your doctor or pharmacist.
- This medicine has been prescribed for you.
- Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Hydralazine 20mg Powder for Concentrate for Solution for Injection/Infusion referred to from now as Hydralazine Injection.

In this leaflet:
1. What Hydralazine Injection is and what it is used for
2. Before you are given Hydralazine Injection
3. How Hydralazine Injection is given
4. Possible side effects
5. How to store Hydralazine Injection
6. Further Information

1. WHAT HYDRALAZINE INJECTION IS AND WHAT IT IS USED FOR

The name of your medicine is Hydralazine Injection. The active ingredient is hydralazine hydrochloride in the form of a powder. Hydralazine hydrochloride belongs to a group of medicines called antihypertensives.

Hydralazine Injection is used to treat very high blood pressure, particularly when this condition occurs in pregnancy or in people with kidney disease. It works by relaxing blood vessels which increases the supply of blood and oxygen to the heart.

2. BEFORE YOU ARE GIVEN HYDRALAZINE INJECTION

You should not be given this medicine if you:
- are allergic to hydralazine, dihydralazine or any of the other ingredients in 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);
- have or have ever had a condition called Systemic Lupus Erythematosus (SLE), an autoimmune condition which causes joint pain, skin rashes and fever;
- suffer from severe tachycardia or right sided heart failure due to increased pressure in the blood vessels of the lungs (or pulmonale);
- suffer from thyrotoxicosis (an excess of thyroid hormones in the blood that can cause a fast heartbeat, sweating, trembling, anxiety, increased appetite, loss of weight and intolerance of heat);
- have a condition known as porphyria.

Hydralazine Injection is not recommended for use in children.

Take special care with Hydralazine Injection if you:
- have had a heart attack in the past three months;
- have angina pectoris, which causes pain in the chest with exercise;
- have cerebrovascular disease (narrowing of the blood vessels in the brain);
- have been told you are a slow acetylator (this means that your body handles some medicines more slowly than other people);
- suffer from thyrotoxicosis (an excess of thyroid hormones in the blood that can cause a fast heartbeat, sweating, trembling, anxiety, increased appetite, loss of weight and intolerance of heat);
- have a condition known as porphyria.

3. HOW HYDRALAZINE INJECTION IS GIVEN

This medicine will be given to you in hospital. Your doctor will decide when and how to treat you with this medicine. It can be given to you in one of 2 ways:
- usually it is injected slowly into your vein using a syringe, this is called an intravenous injection or;
- it may be diluted further and injected very slowly into your vein through a drip (intravenous infusion).

The usual dosage is 5 to 10 mg by intravenous injection, and will be repeated if necessary after 20 to 30 minutes.

Your blood pressure will be taken whilst you are given the injection, and will be repeated if necessary.

4. POSSIBLE SIDE EFFECTS

As with all medicines, Hydralazine Injection can cause side effects, although not everybody gets them.

Like all medicines, Hydralazine Injection can cause side effects, although not everybody gets them. These side effects may affect some people and most are temporary. If any of the above apply to you, or if you are not sure, tell your doctor before receiving Hydralazine Injection.

Taking with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is especially important that you tell your doctor if you are taking:
- medicines for high blood pressure, such as vasodilators (e.g. minoxidil, diazoxide);
- ACE inhibitors (e.g. enalapril, lisinopril, captopril);
- beta-blockers (e.g. propranolol);
- calcium antagonists (e.g. nifedipine, diltiazem);
- medicines for water retention (e.g. diuretics);
- medicines for problems such as depression, including monoamine oxidase inhibitors (MAOs) (e.g. moclobemide, phenelzine, isocarboxazid, tranylcypromine), tricyclic antidepressants (e.g. amitriptyline, clomipramine) or tranquillisers (e.g. diazepam);
- medicines to control pain and inflammation (a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs));
- medicines to control psychoses;
- a specific group of medicines known as nitrates, used to control blood pressure;
- oestrogens (a group of female sex hormones used in contraception and in treating the menopause).

If you are going to have a general anaesthetic you should tell the doctor or dentist in charge that you are taking Hydralazine injection.

Taking Hydralazine Injection with food and drink

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

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding, please tell your doctor before being treated with Hydralazine injection.

Driving and operating machinery

You can drive while being treated with Hydralazine Injection but do not drive until you know how it affects you. It may make you feel dizzy. If it affects you in this way, do not drive or operate any machinery.

5. HOW TO STORE HYDRALAZINE INJECTION

The active ingredient is hydralazine hydrochloride as a powder. They also contain hydrochloric acid (as an inactive ingredient, hydralazine hydrochloride as a powder.

What Hydralazine Injection contain

Hydralazine Injection is provided as a powder in a vial. The solution will be used as soon as it has been made up.

The doctor or nurse will check that the expiry date on the label has not passed before you are given the injection. The solution will be used as soon as you receive it.

Further Information

How to store Hydralazine Injection

It is important that you keep this medicine well away from children. You should also keep it out of the reach of anyone who may misuse it or擅自 take it.

Further information on the safety of this medicine.

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

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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If you are not sure whether a side effect is serious, or if you are not sure whether you should continue taking the medicine, please tell your doctor or pharmacist.

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Like all medicines, Hydralazine Injection 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:
- Frequent effects
  - Abnormal heart beat (palpitations);
  - An unusually fast heart beat;
  - Headaches.
- Occasional side effects
  - Chest pains;
  - Swelling and/or pain in joints, muscle pain;
  - Low blood pressure;
  - Feeling sick and being sick, particularly at the beginning of the treatment or after an increase in dose;
  - Diarrhoea;
  - Flushing.
- Rare side effects
  - Heart failure, swelling;
  - Increased levels of a substance called creatinine in the blood;
  - Breathlessness, breathing difficulties or pain when breathing;
  - Skin rash;
  - Blood in the urine which may be associated with a disease of the kidneys;
  - Presence of protein in the urine;
  - Inflammation or the abnormal functioning of the liver;
  - Watering or sore itchy eyes;
  - A reduction in the number of platelets in the blood which can cause unexplained bruising or rashes;
  - A reduction in red blood cells, which can make you feel tired or breathless with physical exertion;
  - A reduction in certain white blood cells which may make you more susceptible to infections;
  - An increase in other kinds of white blood cells;
  - Fever;
  - Anxiety;
  - Restlessness;
  - Blocked or stuffy nose;
  - Loss of appetite;
  - Weight loss;
  - Dizziness;
  - Generally feeling unwell.

Very rare side effects
- Kidney failure;
- A change in the amount of urine produced;
- A restriction of movement in part of the intestine;
- Episodls of high blood pressure;
- A deficiency of certain white blood cells which can result in fever and ulceration of the mouth and throat;
- An increased number of white blood cells;
- Enlargement of the spleen;
- A reduction in the number of red and white blood cells and platelets in the blood;
- Depression;
- Seeing or hearing things which are not really there (hallucinations);
- Inflammation of the nerves which may cause weakness or numbness especially in your fingers and toes;
- Tingling (pins and needles) in your hands or feet;
- Disease of the lymph nodes;
- Enlarged eye balls.

If you feel very tired, experience unexpected bruising or bleeding, or more infections (e.g. colds and sore throats) than usual please tell your doctor. Your doctor may decide to conduct tests on your blood periodically as a result of these symptoms. If any of the side effects becomes severe, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE HYDRALAZINE INJECTION
The ampoules will be stored in the hospital and they will follow the instructions below.

The ampoules should be protected from light and stored below 30°C.

The doctor or nurse will check that the expiry date on the label has not passed before you are given the injection. The solution will be used as soon as it has been made up.

6. FURTHER INFORMATION
What Hydralazine Injection contain
Each ampoule contains 20 mg of the active ingredient, hydralazine hydrochloride as a powder. They also contain hydrochloric acid (as an inactive ingredient).

What Hydralazine Injection look like and the contents of the pack
Hydralazine Injection is provided as a powder in 2 ml clear glass ampoules. Each pack contains 5 ampoules.

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Amdipharm UK Limited
Capital House, 85 King William Street,
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