

Package leaflet: Information for the patient
Hydralazine 20mg Powder for Concentrate for Solution for Injection/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 , pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet

1. What Hydralazine injection is and what it is used for
2. What you need to know before you are given Hydralazine Injection
3. How you will be given Hydralazine Injection
4. Possible side effects
5. How to store Hydralazine Injection
6. Contents of the pack and other 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 adults with 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. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN HYDRALAZINE INJECTION

You should not be given this medicine:

- if you are **allergic to hydralazine** or any of the other ingredients in this medicine (listed in section 6) (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);
- if you are **allergic to dihydralazine**;
- if you have or have ever had a condition called Systemic Lupus Erythematosus (SLE), an autoimmune condition which causes joint pain, skin rashes and fever;
- if you suffer from severe tachycardia or right sided heart failure due to increased pressure in the blood vessels of the lungs (cor pulmonale);
- if you 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);

- if your heart function is impaired (myocardial insufficiency);
- if you have a condition known as porphyria.
- if you have a condition called dissecting aortic aneurysm.

Warnings and precautions:

Talk to your doctor or pharmacist or nurse before using Hydralazine Injection

- if you have had a heart attack in the past three months;
- if you have coronary heart disease;
- if you have angina pectoris, which causes pain in the chest with exercise;
- if you have cerebrovascular disease (narrowing of the blood vessels in the brain);
- if you have been told you are a slow acetylator (this means that your body handles some medicines more slowly than other people);
- if you suffer from any serious liver or kidney problems;
- if you are experiencing fever, loss of appetite, weight loss, tiredness, general body pain, coughing which may produce tarry black deposits or blood, swelling of arms, hands, legs, feet and ankles, blood in urine while on treatment with Hydralazine. Talk to your doctor or nurse or pharmacist immediately.
- if you have blockage of one or more arteries that supply blood to the heart (coronary heart disease).
- if you have had blood tests before starting treatment

Children

Hydralazine Injection is not recommended for use in children. In rare cases Hydralazine Injection may be used with extreme caution to treat children.

Other medicines and Hydralazine Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 (MAOIs) (e.g. moclobemide, phenelzine, isocarboxazid, tranlycypromine); 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));
- corticosteroids (e.g. prednisolone or prednisone);
- 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.

Hydralazine Injection with food , drink and alcohol

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

Taking Hydralazine Injection with food may decrease the amount of the medicine in your system, therefore, take it before food.

Pregnancy and breast-feeding

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 using this medicine.

Driving and using machines

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 or impair your reactions. If it affects you in this way, **do not** drive or operate any machinery.

3. HOW YOU WILL BE GIVEN HYDRALAZINE INJECTION

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 recommended dose 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 receiving treatment and the dose adjusted to make sure that you have gradual fall in your blood pressure to normal levels.

Use in children

In the rare cases where rapid treatment proves indispensable in a child, Hydralazine injection should be used with extreme caution. The initial dose is 0.1-0.5 mg/kg body weight administered intravenously over 1-2 min with repeat doses every 30-90 min as required, up to a maximum daily dose of 3.5 mg/kg body weight

If you are given more Hydralazine Injection than you should

Symptoms of overdose include a faster or irregular heartbeat, low blood pressure, feeling sick, dizziness, and sweating. Chest pain, headache, vomiting and losing consciousness are also possible symptoms. As this medicine is given to you in hospital it is very unlikely that an overdose will happen. 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:

- Fever, loss of appetite, weight loss, coughing which may produce dark tarry black deposits or blood, swelling of arms, hands, legs, feet and ankles, blood in urine
- 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.
- Kidney failure (e.g. changes in urine, swelling of legs, ankles or feet, shortness of breath, tiredness and nausea).

Other side effects may include:

Very common (may affect more than 1 in 10 people)

- Abnormal heartbeat (palpitations);
- An unusually fast heartbeat;
- Headaches.

Common (may affect up to 1 in 10 people)

- 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 (may affect up to 1 in 1,000 people)

- Heart failure, swelling;
- Increased levels of a substance called creatinine in the blood;
- Breathlessness, breathing difficulties or pain when breathing;
- Liver enlargement
- 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;
- Watery or sore itchy eyes (conjunctivitis);
- 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;
- Fever;

- Anxiety;
- Restlessness;
- Blocked or stuffy nose;
- Loss of appetite;
- Weight loss;
- Dizziness;
- Generally feeling unwell.

Isolated cases

- A change in the amount of urine produced;
- A restriction of movement in part of the intestine;
- 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 and liver;
- 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;
- The inability to completely or partially empty the bladder;
- Opposite effect of medical treatment (episodes of high blood pressure);
- An increase in other kinds of white blood cells.

Not known (frequency cannot be estimated from the available data)

- Involuntary shaking or movement (tremors)
- Inflammation of veins and arteries (Systemic vasculitis) which may lead to a rare medical syndrome involving bleeding in the lungs and kidney damage (Pulmonary renal syndrome).

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.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE HYDRALAZINE INJECTION

The Vials will be stored in the hospital and they will follow the instructions below.

Store the Vials in the original package in order to protect from light. Store below 25°C.
Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of the month. The solution will be used as soon as it has been made up.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hydralazine Injection contains

Each vial contains 20 mg of the active ingredient, hydralazine hydrochloride as a powder. They also contain hydrochloric acid, water for injection and nitrogen (as an inactive ingredient).

What Hydralazine Injection looks like and contents of the pack

Hydralazine Injection is provided as a white to yellow powder in 3 ml clear glass Vials.
Each pack contains 5 Vials.

Marketing Authorisation Holder

Amdipharm UK Limited,
Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, United Kingdom

Alternate Manufacturer

FAMAR HEALTH CARE SERVICES
MADRID S.A.U.
Avda. de Leganés, 62 - 28923
Alcorcón (Madrid)
España

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