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

Very rare (may affect up to 1 in 10,000 people):
- A change in the amount of urine produced, the inability to completely or partially empty the bladder
- 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
- 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
- Opposite effect of medical treatment (episodes of high blood pressure).

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 Website: 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.

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5 How to store Hydralazine tablets
Keep this medicine out of the sight and reach of children.
Do not store above 25°C. Store in the original container.
Do not use Hydralazine tablets after the expiry date which is stated on the label/ carton. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information
What Hydralazine tablets contain
- The active substance is hydralazine hydrochloride.
- Each film-coated tablet contains either 25mg or 50mg of the active substance.
- The other ingredients are polyvidone, disodium edetate, microcrystalline cellulose (E460), magnesium stearate.
- Tablet coating: hypromellose (E464), titanium dioxide (E171).
  25mg also contains: lactose monohydrate, macrogol, glycerol triacetate (E1518), iron oxide (E172).
  50mg also contains: polyethylene glycol, carmoisine aluminium lake azorubine (E122).

What Hydralazine tablets look like and contents of the pack
25mg tablets are ivory, circular, biconvex, film-coated tablets impressed 'C' on one face and the identifying letters 'HY' on the reverse.

50mg tablets are pink, circular, biconvex, film-coated tablets impressed 'C' on one face and the identifying letters 'HZ' on the reverse.

Pack size: 56.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in April 2024

accord

Package leaflet: Information for the patient

Hydralazine 25mg and 50mg tablets

Read all of this leaflet carefully before you start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Hydralazine tablets are and what they are used for
2 What you need to know before you take Hydralazine tablets
3 How to take Hydralazine tablets
4 Possible side effects
5 How to store Hydralazine tablets
6 Contents of the pack and other information

1 What Hydralazine tablets are and what they are used for
Hydralazine hydrochloride belongs to a group of medicines called antihypertensives.
Hydralazine is used to treat high blood pressure and heart failure.
It works by relaxing blood vessels and increasing the supply of blood and oxygen to the heart.

2 What you need to know before you take Hydralazine tablets
Do not take Hydralazine tablets 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)
- suffer from a **racing heartbeat** (tachycardia)
- have **heart failure** caused by narrowing of blood vessels or heart valves (aortic or mitral stenosis), high blood pressure in blood vessels supplying the lungs (pulmonary hypertension) or inflammation of the heart (constrictive pericarditis)
- have **heart failure** with a normal or increased output of blood from the heart (e.g. in thyrotoxicosis)
- have or have ever had a condition called **Systemic Lupus Erythematosus (SLE)** an autoimmune condition which causes joint pain, skin rashes and fever, or any related disease
- have swelling in a blood vessel wall **(aortic aneurysm)**
- have (or a relative has) an inherited disorder of the red blood pigment haemoglobin **(porphyria).**

Warnings and precautions
Talk to your doctor or pharmacist before taking Hydralazine tablets if you:
- have had a heart attack in the past three months
- have blockage of one or more arteries that supply blood to the heart (coronary heart disease)
- 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)

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- suffer from any serious liver or kidney problems
- 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.

Tests
If you are taking long-term Hydralazine treatment, your doctor may want to carry out blood and urine tests every 6 months.

Children and adolescents
Not recommended for use in children or adolescents.

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

It is especially important to tell your doctor if you are taking:
- medicines for high blood pressure, such as vasodilators (e.g. minoxidil or diazoxide)
- ACE inhibitors (e.g. enalapril, lisinopril, captopril)
- beta-blockers (e.g. propranolol)
- calcium antagonists (e.g. nifedipine or diltiazem)
- medicines for water retention (e.g. diuretics)
- medicines for problems such as depression, including monoamine oxidase inhibitors (MAOIs) (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))
- 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)
- muscle relaxants (e.g. baclofen, tizanidine).

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

Hydralazine tablets with alcohol
It is advisable not to drink alcohol whilst taking Hydralazine tablets as it may affect you more than usual.
Taking Hydralazine 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, please tell your doctor before taking Hydralazine Tablets.

Driving and using machines
You can drive while taking Hydralazine but do not drive until you know how the tablets affect you. They may make you feel dizzy. If they affect you in this way, **do not** drive or operate any machinery.

Hydralazine 25mg tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as the 25mg tablets contain lactose.

Hydralazine 50mg tablets contain E122
The 50mg tablets contain the colour E122 which may cause allergic reactions.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Hydralazine tablets
Always take Hydralazine tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow these tablets **with water.**

The recommended dose is:
Adults (including the elderly):
Hypertension: Initially 25mg twice a day or 50mg once a day. Your doctor may gradually increase this, up to a maximum of 200mg a day. Your doctor will decide on the best dose for you.
Chronic congestive heart failure: Treatment should be started in hospital and dosages can vary. The maintenance dose is 50mg - 75mg four times a day.

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Use in children: Not recommended.

If you take more Hydralazine tablets than you should
If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include low blood pressure, a faster or irregular heartbeat, decreased blood flow to the heart and unconsciousness (coma).

If you forget to take Hydralazine tablets
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Hydralazine tablets
Do not stop treatment early because an increase in blood pressure may occur. Talk to your doctor before you stop taking the tablets and follow their advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

Stop taking this medicine and seek immediate medical advice if you notice the following serious side effects:
Common (may affect up to 1 in 10 people):
- SLE-type syndrome, which can cause symptoms such as joint pain, fever, change in blood count and skin rash.

Rare (may affect up to 1 in 1,000 people):
- Allergic reactions including itching, skin rash, inflammation of the walls of small blood vessels and difficulty in breathing.
- Heart failure, swelling.
- A reduction in certain white blood cells which may make you more susceptible to infections.
- A reduction in the number of platelets in the blood which can cause unexplained bruising or rashes.
- Yellowing of the skin and whites of the eyes, which may indicate problems with the liver such as jaundice and hepatitis.

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Very rare (may affect up to 1 in 10,000 people):
- A reduction in the number of red and white blood cells and platelets in the blood.
- Kidney failure (e.g. changes in urine, swelling of legs, ankles or feet, shortness of breath, tiredness and nausea).

Not known (frequency cannot be estimated from the available data):
- 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). Symptoms include 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.

Other side effects may include:

Very common (may affect more than 1 in 10 people):
- Abnormal heart beat (palpitations)
- An unusually fast heart beat
- 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):
- A reduction in red blood cells, which can cause pale yellow skin and weakness or breathlessness.
- Increased levels of substances 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
- Watering or sore itchy eyes (conjunctivitis)
- Fever
- Anxiety
- Restlessness

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