Hydralazine All Strengths Tablets PIL - United Kingdom

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

What is Hydralazine tablets

The active substance is hydralazine hydrochloride.

Each film-coated tablet contains either 25mg or 50mg of the active substance.

The other ingredients are polyvidone, sodium edetate, microcrystalline cellulose (E460), magnesium stearate.

Tablet coating: hypromellose (E464), titanium dioxide (E171), 25mg also contains: lactose monohydrate, magnesium stearate, aluminium lake azorubine (E122).

What do Hydralazine tablets look like and contents of the pack

25mg tablets are oval, 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.

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Warnings and precautions

Talk to your doctor or pharmacist before taking Hydralazine tablets if you have:

- have had a heart attack in the past three months
- have 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)

Take Hydralazine tablets if you have:

- an allergy to hydralazine, dihydralazine or any of the other ingredients in this medicine (listed in section 6)
- a racing heartbeat (tachycardia)
- 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)
- heart failure with a normal or increased output of blood from the heart (e.g. in thyrotoxicosis)
- systemic lupus erythematosus (SLE) or any related disease
- swelling in a blood vessel wall (aortic aneurysm)
- (or a relative has) an inherited disorder of the red blood pigment haemoglobin (porphyria).

What do Hydralazine tablets contain

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• Each film-coated tablet contains either 25mg or 50mg of the active substance.

• The other ingredients are polyvidone, sodium edetate, microcrystalline cellulose (E460), magnesium stearate.

• Tablet coating: hypromellose (E464), titanium dioxide (E171), 25mg also contains: lactose monohydrate, magnesium stearate, aluminium lake azorubine (E122).

What is Hydralazine tablets used for

Hydralazine belongs to a group of medicines called vasodilators. These medicines relax the muscles of artery walls and cause blood vessels to expand.

Hydralazine tablets are used to:

- treat moderate to severe high blood pressure (with or without a beta-blocker or diuretic medicine)

- manage moderate to severe congestive heart failure (where use of other medicines alone is not enough).

How to stop Hydralazine tablets

Do not stop Hydralazine tablets without speaking to your doctor or pharmacist.

What should I do if I take too much Hydralazine tablets

If you take too much Hydralazine tablets, talk to a doctor or pharmacist and show them the pack.

What are the possible side effects of taking Hydralazine tablets

Some side effects do not always mean that you have to stop the medicine. Your doctor or pharmacist will probably decide whether you need to stop the medicine.

• 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
• Enlargement of the spleen
• 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 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.

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suffer from any serious liver or kidney problems.

**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 dihydrochloride)
- ACE inhibitors (e.g. enalapril, lisinopril, captopril)
- Beta-blockers (e.g. propranolol)
- calcium antagonists (e.g. nifedipine or dilutiazem)
- 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 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).

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.

**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 you have an intolerance to some sugars, contact your doctor before taking this medicine, 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’.

**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.

Speak to your doctor before drinking alcohol with this medicine.

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.
  - Use in children: Not recommended.

**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 serious side effects:**
- Common (may affect up to 1 in 10 people):
  - 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 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.

**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, racing heartbeat, decreased blood flow to the heart, irregular heartbeat, 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.

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Hydralazine Tablets are used to:

- have been told you are a slow acetylator (this means that your body handles some medicines more slowly than other people)
- have had a heart attack in the past three months
- have coronary heart disease
- have angina pectoris, which causes pain in the chest with overexertion
- have cerebrovascular disease (narrowing of the blood vessels in the brain)
- have been told you are at risk of a stroke
- are pregnant (it may harm your baby, even if you only take Hydralazine tablets for a short time)
- are breast feeding (it may harm your baby, even if you only take Hydralazine tablets for a short time)

In rare cases, Hydralazine tablets may cause a disease. This may affect:

- 1. A deficiency of certain white blood cells which can result in fever and ulceration of the mouth and throat
- 2. An increased number of white blood cells
- 3. Enlargement of the spleen
- 4. Depression
- 5. Seeing or hearing things which are not really there (hallucinations)
- 6. Inflammation of the nerves which may cause weakness or numbness especially in your fingers and toes
- 7. Tingling (pins and needles) in your hands or feet
- 8. Disease of the lymph nodes
- 9. Enlarged eye balls
- 10. 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. See section 4.

Reporting any suspected side effect

You can report suspected side effects 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.

What Hydralazine tablets look like and contents of the pack

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: polyvinyl alcohol, 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, carmosine aluminium lake azorubine (E122).

Possible side effects

• Opposite effect of medical treatment (episodes of high blood pressure)
• Disease of the lymph nodes
• Seeing or hearing things which are not really there (hallucinations)
• Depression
• Enlargement of the spleen
• A deficiency of certain white blood cells
• Generally feeling unwell.
• Loss of appetite
• Weight loss
• Dizziness
• Generally feeling unwell.