

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

HYDRALAZINE HCl 25 KIARA (Tablets)

Hydralazine hydrochloride

Contains Sugar (Sucrose)

HYDRALAZINE HCl 50 KIARA (Tablets)

Hydralazine hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking HYDRALAZINE HCl KIARA tablets.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **HYDRALAZINE HCl KIARA tablets have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

1. What HYDRALAZINE HCl KIARA is and what it is used for
2. What you need to know before you take HYDRALAZINE HCl KIARA
3. How to take HYDRALAZINE HCl KIARA
4. Possible side effects
5. How to store HYDRALAZINE HCl KIARA
6. Contents of the pack and other information

1. What HYDRALAZINE HCl KIARA is and what it is used for

Hydralazine belongs to the general class of medicines called antihypertensives. It is used to treat various forms of high blood pressure (hypertension). HYDRALAZINE HCl KIARA may also be used for other conditions as determined by your doctor.

2. What you need to know before you take HYDRALAZINE HCl KIARA

Do not take HYDRALAZINE HCl KIARA:

- If you are hypersensitive (allergic) to hydralazine hydrochloride or any of the other ingredients of HYDRALAZINE HCl KIARA (listed in section 6).
- If you have an excessive heart rate also called tachycardia.
- If you are pregnant or breastfeeding a baby.

Warnings and precautions:

Take special care with HYDRALAZINE HCl KIARA:

Tell your doctor or pharmacist before taking this medicine:

- If you recently had a heart attack (myocardial infarction).
- If you have a heart or blood vessel disease.
- If you had a stroke - lowering blood pressure may make problems resulting from this condition worse.
- If your liver or kidney function is impaired.

Other medicines and HYDRALAZINE HCl KIARA:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor, pharmacist or other healthcare professional if you are taking any of the following medicines:

- Other medicine to treat your high blood pressure.
- Anti-inflammatory drugs (NSAIDs).

- Antidepressants (tricyclic, e.g. amitriptyline, or monoamine oxidase inhibitors, e.g. phenelzine, iproniazid, isocarboxazid, nialamide and tranylcypromine).

HYDRALAZINE HCl KIARA with food and drink:

The tablets should be swallowed whole with a glass of water. Do not crush or chew the tablets.

This medication should be taken with meals.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. Do not use HYDRALAZINE HCl KIARA if you are pregnant. Hydralazine passes into the breast milk. Mothers who are taking this medicine and who wish to breastfeed should discuss this with their doctor.

Driving and using machinery:

HYDRALAZINE HCl KIARA may cause some people to become dizzy or have headaches. Do not drive or operate any machinery before you know how this medicine affects you.

HYDRALAZINE HCl KIARA contains sucrose:

HYDRALAZINE HCl 25 KIARA contains sucrose crystals which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take HYDRALAZINE HCl KIARA

Do not share medicines prescribed for you with any other person.

Always take HYDRALAZINE HCl KIARA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

It is recommended that you take these tablets with meals.

The usual dose for adults is:

25 to 75 mg of hydralazine hydrochloride daily in divided doses.

Your doctor or healthcare professional may decide to increase the dose over a period of 2 weeks to a maximum of 200 mg daily.

Your doctor will tell you how long your treatment with HYDRALAZINE HCl KIARA will last. Do not stop treatment early because this may worsen your current condition.

If you have the impression that the effect of HYDRALAZINE HCl KIARA is too strong or too weak, tell your doctor or pharmacist.

If you take more HYDRALAZINE HCl KIARA than you should:

In the event of an overdose you may experience headaches, dizziness, nausea, vomiting, fast heartbeat or watery eyes. Contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take HYDRALAZINE HCl KIARA:

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

HYDRALAZINE HCl KIARA can have side effects. The following side effects have been reported.

Not all side effects reported for HYDRALAZINE HCl KIARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HYDRALAZINE HCl KIARA, please consult your doctor, pharmacist or other healthcare professional for advice.

Contact your doctor as soon as possible if any of the following side effects occur:

The following side effects have been reported less frequently:

- ♦ Blisters, rash or itching of the skin.
- ♦ Chest pain and stomach pain.
- ♦ General feeling of discomfort, illness or weakness.
- ♦ Weakness in hands or feet.
- ♦ Swelling of feet, lower legs or lymph glands.
- ♦ Blood disorder (abnormalities in blood when blood is tested).
- ♦ High fever.
- ♦ Hallucination.
- ♦ Heart attack.

You may experience other side effects that usually do not need medical attention. However, check with your doctor if any of the following side effects continue or are bothersome.

The following side effects have been reported frequently:

- Diarrhoea.
- Fast heartbeat.
- Headache.
- Nausea or vomiting.
- Loss of sensation.
- Disorder of peripheral nerves.

The following side effects have been reported less frequently:

- Dizziness.
- Redness or flushing of face.
- Stuffy nose.
- Watery eyes.

- Fatigue.
- Joint and muscle pains.
- Depression.
- Agitation.
- Anxiety.
- Yellow eyes.
- Liver and kidney problems.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of HYDRALAZINE HCl KIARA.

5. How to store HYDRALAZINE HCl KIARA

Keep well closed. Store at or below 25 °C.

Protect the medicine from light.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the container, blister or label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HYDRALAZINE HCl KIARA contains

HYDRALAZINE HCl 25 KIARA

The active substance is hydralazine hydrochloride. The other ingredients are copolymers of pyrrolidone & vinyl acetate, colloidal silicon dioxide, hydroxypropylmethylcellulose, magnesium stearate, maize starch,

microcrystalline cellulose, povidone K30, polyethylene glycol, sucrose crystals, talc and the colourants titanium dioxide (CI 77891) and dispersed yellow (15093).

HYDRALAZINE HCl 25 KIARA tablets contain sugar (22, 95 mg sucrose crystals).

HYDRALAZINE HCl 50 KIARA

The active substance is hydralazine hydrochloride. The other ingredients are colloidal anhydrous silica, magnesium stearate, maize starch, methylhydroxybenzoate (preservative), povidone K30, talc and the colourant opadry red OY-35003.

HYDRALAZINE HCl 50 KIARA tablets are sugar free.

What HYDRALAZINE HCl look like and contents of the pack

HYDRALAZINE HCl 25 KIARA: Shiny, pale yellow, round, biconvex, sugar coated tablets.

HYDRALAZINE HCl 50 KIARA: Round, biconvex, pink film-coated tablets.

HYDRALAZINE HCl 25 KIARA tablets are packed in amber glass bottles, securitainers and blister strips containing 30, 56, 84, 100 or 500 tablets.

HYDRALAZINE HCl 50 KIARA tablets are packed in amber glass bottles containing 30, 100 or 500 tablets. These tablets are also packed in securitainers, sealed aluminium bags and blister strips containing 30, 56, 84, 100 or 500 tablets.

Holder of Certificate of Registration

Kiara Health (Pty) Ltd

72 Steel Road

Spartan

Kempton Park

1619

This leaflet was last revised in

18 March 2021

Registration numbers

HYDRALAZINE HCl 25 KIARA: Q/7.1.3/269

HYDRALAZINE HCl 50 KIARA: Q/7.1.3/270

Additional countries registration details:

Country	Product name	Scheduling status (or Category of distribution)	Registration number
Botswana	HYDRALAZINE HCl 25 KIARA	S2	B9309070
	HYDRALAZINE HCl 50 KIARA	S2	B9309075
Namibia	HYDRALAZINE HCl 25 KIARA	NS2	90/7.1.3/001477
	HYDRALAZINE HCl 50 KIARA	NS2	90/7.1.3/001478

ATC Code: C02DB01 - Hydrazinophthalazine derivatives

Name and address of manufacturer:

Kiara Health (Pty) Ltd

72 Steel Road

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South Africa