SCHEDULING STATUS: S3

1. NAME OF THE MEDICINE
HYDRALAZINE HCl 25 KIARA (tablets)
HYDRALAZINE HCl 50 KIARA (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each HYDRALAZINE HCl 25 KIARA tablet contains 25 mg hydralazine hydrochloride.
Each HYDRALAZINE HCl 50 KIARA tablet contains 50 mg hydralazine hydrochloride and 0,5 % *m/m* methyl hydroxybenzoate as preservative.
HYDRALAZINE HCl 25 KIARA contains sugar (22,95 mg sucrose crystals).
HYDRALAZINE HCl 50 KIARA tablets are sugar free.

3. PHARMACEUTICAL FORM
HYDRALAZINE HCl 25 KIARA: Shiny, pale yellow, round, biconvex, sugar coated tablets.
HYDRALAZINE HCl 50 KIARA: Round, biconvex, pink film-coated tablets.

4. CLINICAL PARICULARS
4.1 Therapeutic indications
Various forms of hypertension including essential hypertension, hypertension with renal involvement and malignant hypertension.

4.2 Posology and method of administration
The usual initial oral dose of HYDRALAZINE HCl KIARA is 25 to 75 mg daily in divided doses increased over a period of 2 weeks, according to the patient's response, to a maximum of 200 mg daily.

Hepatic and renal impairment:
The dose of HYDRALAZINE HCl KIARA should be reduced or the dosage interval prolonged in patients with hepatic or renal impairment.

Hypertension:
The dosage must always be adjusted to the individual requirements of the patient and the following recommendations adhered to:

Adults:
Treatment should begin with low doses of hydralazine, which depending on the patient's response should be increased stepwise in order to achieve an optimal therapeutic effect and to avoid unwanted effects as far as possible.

Hydralazine is given in a twice daily regimen and the usual starting dosage of 25 mg twice daily is generally sufficient.

This dosage can be increased as required within the effective maintenance dosage range of 50 to 200 mg per day. However, the dose should not be increased above 100 mg per day without determining the patient's acetylator phenotype and in women (see "4.4 Special warnings and precautions for use").

Special Populations:
Renal impairment and hepatic impairment (all indications):
In patients with moderate to severe renal impairment (creatinine clearance < 30 mℓ/min or serum creatinine concentration > 2,5 mg/100 mℓ or 221 µmol/ℓ) or hepatic dysfunction, the dosage or the dosing interval must be adapted according to the clinical response to avoid accumulation of the "apparent" active substance (see "4.4 Special warnings and precautions for use").

4.3 Contraindications
- Hypersensitivity to HYDRALAZINE HCl KIARA or any of the ingredients.
- Pregnancy and lactation (see "4.6 Fertility, Pregnancy and Lactation").
- Idiopathic systemic lupus erythematosus (SLE) and related diseases.
- Severe tachycardia and heart failure with a high cardiac output (e.g. in thyrotoxicosis).
- Myocardial insufficiency due to mechanical obstruction (e.g. in the presence of aortic or mitral stenosis or constrictive pericarditis).
- Isolated right-ventricular heart failure due to pulmonary hypertension (cor pulmonale).
- Dissecting aortic aneurysm.

4.4 Special warnings and precautions for use
HYDRALAZINE HCl KIARA induced vasodilatation produces myocardial stimulation. It should therefore be used with caution in patients with ischaemic heart disease since it can increase angina and it should not be given to patients following myocardial infarction until their condition has stabilised. Patients with suspected or confirmed ischaemic heart disease should be given HYDRALAZINE HCl KIARA under cover of a β-blocker, which should be started a few days before the HYDRALAZINE HCl KIARA, in order to prevent myocardial stimulation.
If given to patients with heart failure they should be monitored for orthostatic hypotension and tachycardia during the initial stages of therapy, preferably in hospital. If treatment with HYDRALAZINE HCl KIARA is to be stopped in patients with heart failure it should generally be withdrawn gradually.

HYDRALAZINE HCl KIARA should be used with caution in patients with cerebrovascular disorders.

The use of hydralazine can result in sodium and fluid retention, producing oedema and reduced urinary volume. These unwanted effects are best prevented by concomitant administration of a diuretic.

The dose of HYDRALAZINE HCl KIARA should be reduced or the dosage interval prolonged in patients with hepatic or renal impairment.
In particular, renal symptoms are less frequent than in idiopathic SLE and pleuro-pulmonary symptoms, as well as pericarditis, are more frequent. Since such reactions tend to occur more frequently the higher the dosage and the longer the duration of the medication, and since they are also more common in slow acetylators, it is recommended that for maintenance therapy the lowest dosage that still proves effective should be used. If 100 mg daily fails to elicit an adequate clinical effect, the patient's acetylator status should be evaluated.

Slow acetylators and women run a greater risk of developing an SLE-like syndrome. In such patients every effort should therefore be made not to exceed a dosage of 100 mg daily; a careful watch should also be kept for clinical signs and symptoms suggestive of SLE-like syndrome.

Rapid acetylators, by contrast, often respond inadequately even to dosages of 100 mg daily. In these patients, the dosage can be raised with only a slightly increased risk of a SLE-like syndrome.

During long-term treatment with HYDRALAZINE HCl KIARA it is advisable to determine the antinuclear factors (ANF) and to carry out urine analyses at intervals of approximately 6 months. Microhaematuria and/or proteinuria, in particular together with positive titres of ANF, may be initial signs of immune-complex glomerulonephritis associated with the SLE-like syndrome. If overt clinical signs and symptoms develop, the medicine should be withdrawn at once.

Pericardial effusion:
HYDRALAZINE HCl KIARA should be used with caution in patients with a history of coronary disease. Reduced doses of HYDRALAZINE HCl KIARA should be given to patients who are slow acetylators. Hypotension may occur during anaesthesia in patients being treated with HYDRALAZINE HCl KIARA.

HYDRALAZINE HCl 25 KIARA contains sucrose crystals, which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction
The hypotensive effect of HYDRALAZINE HCl KIARA may be enhanced by other medicines with a hypotensive action. Epinephrine (adrenaline) should not be given to antagonise the hypotensive effects of HYDRALAZINE HCl KIARA since it enhances the cardiac acceleration effects.
Caution should be observed if HYDRALAZINE HCl KIARA is administered concurrently with monoamine oxidase inhibitors or tricyclic antidepressants.
The hypotensive effects of HYDRALAZINE HCl KIARA may be enhanced by thiazide diuretics and by β-adrenergic blocking agents which may also diminish the cardiac accelerating effects.

Concomitant treatment with other vasodilators, calcium antagonists, ACE inhibitors, diuretics, antihypertensives, tricyclic antidepressants, and major tranquillisers, as well as the consumption of alcohol, may potentiate the blood-pressure-lowering effect of hydralazine. In particular, administration of HYDRALAZINE HCl KIARA shortly before or after diazoxide may give rise to marked hypotension. MAO inhibitors should be used with caution in patients receiving HYDRALAZINE HCl KIARA.

Concurrent administration of HYDRALAZINE HCl KIARA with β-blockers, subject to a strong first-pass effect, may increase their bioavailability.
Downward dosage adjustment of these drugs may be required when they are given concomitantly with HYDRALAZINE HCl KIARA.

Anti-inflammatory drugs, NSAIDs, may reduce the antihypertensive effects of HYDRALAZINE HCl KIARA.

Concurrent intake of food has been found to decrease the bioavailability of HYDRALAZINE HCl KIARA and also to reduce vasodilator effect.

4.6 Fertility, Pregnancy and Lactation
HYDRALAZINE HCl KIARA is contraindicated in pregnancy and lactation as teratogenicity has been demonstrated in animals.
HYDRALAZINE HCl KIARA is distributed into breast milk. HYDRALAZINE HCl KIARA should not be used by mothers breastfeeding their infants.

4.7 Effects on ability to drive and use machines
Dizziness or hypotension may occur with HYDRALAZINE HCl KIARA, it is therefore advisable to exercise caution when driving or operating machinery.

4.8 Undesirable effects
Some of the unwanted effects listed below such as tachycardia, palpitations, anginal symptoms, flushing, headache, dizziness, nasal congestion and gastrointestinal disturbances are commonly seen at the start of treatment especially if the dosage is raised rapidly. However, such reactions generally subside in the further course of treatment.

Blood and the lymphatic system disorders:
Less frequent: Blood disorders, including agranulocytosis, leucopenia and purpura, lymphadenopathy, anaemia, neutropenia, thrombocytopenia with or without purpura, haemolytic anaemia, leucocytosis, pancytopenia, splenomegaly.

Immune system disorders:
Frequent: SLE-like syndrome (sometimes resulting in a fatal outcome – see "4.4 Special warnings and precautions for use").
Less frequent: A more serious toxic reaction which may occur following the prolonged use of large doses is a condition resembling either early rheumatoid arthritis or systemic lupus erythematosus. The rheumatic condition usually disappears when the HYDRALAZINE HCl KIARA is withdrawn or the dosage reduced.
The severe erythematosus conditions may be controlled with corticosteroids.
Hypersensitivity reactions such as urticaria, pruritus, vasculitis, eosinophilia, hepatitis.

Metabolism and nutrition disorders:
Frequent: Anorexia.

Psychiatric disorders:
Less frequent: Agitation, anxiety, depression, hallucinations.

Nervous system disorders:
Frequent: Severe headache.
Less frequent: Peripheral neuritis with numbness, tingling of the extremities and urticaria. Emotional depression, anxiety and tremor may occur.

Eye disorders:
Less frequent: Conjunctivitis, lacrimation, exophthalmos.

Ear and labyrinth disorders:
Less frequent: Vertigo.

Cardiac disorders:
Frequent: Tachycardia, palpitations and angina pectoris.
Less frequent: Congestive cardiac failure.

Vascular disorders:
Less frequent: Postural hypotension, local oedema, flushing of face.

Respiratory, thoracic and mediastinal disorders:
Less frequent: Nasal congestion, dyspnoea, pleural pain.

Gastrointestinal disorders:
Frequent: Nausea, vomiting and diarrhoea, gastrointestinal disorder.
Less frequent: Paralytic ileus, constipation.

Hepato-biliary disorders:
Less frequent: Hepatitis, jaundice, hepatomegaly, abnormal hepatic function, sometimes in association with hepatitis.

Skin and subcutaneous tissue disorders:
Less frequent: Pruritus, skin rashes, cutaneous vasculitis.

Musculoskeletal, connective tissue and bone disorders:
Less frequent: Muscle cramps, arthralgia, joint swelling, myalgia.

Renal and urinary disorders:
Less frequent: Urinary retention, glomerulonephritis, proteinuria, plasma creatinine increased, haematuria, acute renal failure.

General disorders and administrative site conditions:
Less frequent: Fever, malaise, dizziness.

4.9 Overdose
Headaches, dizziness, palpitations, nausea, vomiting, nasal congestion, flushing, lacrimation, tremor, muscle cramps, disorientation. Hypotension with tachycardia leading to coronary pain, anuria and coma.
If overdosage occurs, the stomach should be emptied by aspiration and lavage.
Further treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification:
A 7.1.3 Other hypotensives
ATC Code: C02DB02 - Hydrazinophthalazine derivatives
Hydralazine is an antihypertensive medicine which acts predominantly by causing direct peripheral vasodilation. Hydralazine tends to increase renal and cerebral blood flow and its effect on diastolic pressure is more marked than on systolic pressure. It has more marked action on the standing than the supine blood pressure. It produces cardiac stimulation probably due to a reflex response to the fall in blood pressure.

5.2 Pharmacokinetic properties
Absorption and plasma concentrations:
Hydralazine given orally is well and completely absorbed from the gastrointestinal tract and the absorption is variable according to the acetylation status of the individual. The maximum serum concentration of hydralazine after single oral administration of 50 mg hydralazine was found to be 229 ± 20 ng/mℓ and 148 ± 15 ng/mℓ in slow and fast acetylators, respectively. Peak plasma concentrations are reached within 1 hour in most cases. Concurrent intake of food has been found to decrease the bioavailability of hydralazine and also to reduce vasodilator effect.

Orally administrated hydralazine undergoes a dose-dependent first-pass effect (systemic bioavailability: 26 to 55 %), this first-pass effect being dependent on the individual's acetylator status. Hydralazine exhibits non-linear pharmacokinetics and it is attributed to the saturable first pass effects.

Distribution:
Hydralazine is primarily present as hydrazine conjugate with pyruvic acid in plasma. Hydralazine becomes bound to plasma proteins (chiefly albumin) to the extent of 88 to 90 %. The volume of distribution of hydralazine was determined as 1,5 ± 1,0 ℓ/kg. Hydralazine is rapidly distributed in the body and displays a specific affinity for muscle tissue of the arterial walls. Hydralazine crosses the placental barrier and also passes into the breast milk.

Biotransformation:
After oral administration the pattern of metabolites depends mainly on the subject's acetylator status.

Systemic metabolism in the liver is by hydroxylation of the ring system and conjugation with glucuronic acid and acetylator status does not affect elimination. The major metabolites are the acetylation product (3-methyl-1,2,4-triazolo-(3,4a)phtalazine) hydralazine pyruvic acid hydrazine, which is the major plasma metabolite; and NAc-HPZ (4-(2-acetylhydrazino) phtalazin-1-one, N-AcHPZ (4-(2-acetylhydrazino) which is mostly found in the urine and this metabolite was found to be the relevant indicator for the drug-related phenotype.

Elimination:
The plasma half-life generally ranges from 2 to 3 hours, but in rapid acetylators it is shorter, averaging 45 minutes. In patients with impaired renal function, the plasma half-life is prolonged to up to 16 hours at a creatinine clearance of < 20 mℓ/min.

Hydralazine and its metabolites are rapidly excreted by the kidney. Within 24 hours after an oral dose, approximately 80 % of the dose can be recovered in the urine. The bulk of the hydralazine excreted is in the form of acetylated and hydroxylated metabolites, some of which are conjugated with glucuronic acid; 2 to 14 % is excreted as "apparent" hydralazine. Advancing age does not affect either the blood concentration or the systemic clearance of "apparent" hydralazine. Renal elimination may however be affected insofar as kidney function diminishes with age.

Mutagenicity:
Hydralazine, in cytotoxic concentrations, induces gene mutations in bacteria, yeasts and *Drosophila*, and in mammalian cells *in vitro*. No clear mutagenic effects including chromosomal aberrations have been detected *in vivo* in a large number of test systems.

Under *in vitro* conditions, the formation of reactive metabolites/intermediates is favoured, so that DNA damage may occur. *In vivo*, however, i.e. under normal metabolic conditions, there is intense detoxification of potentially toxic intermediates. Consequently, the genotoxic/mutagenic risk for man is estimated to be very low.

Carcinogenicity:
In a 2 year carcinogenicity study in rats, microscopic examination of the liver revealed some increase in the incidence of benign neoplastic nodules at oral doses (gavage) of 30 and 60 mg/kg. No such nodules were found at 15 mg/kg. The males of the 60 mg/kg dose group also showed benign tumours of testicular interstitial cells.

Studies of the carcinogenic potential of hydralazine in rats do not suggest a specific carcinogenic risk at therapeutic doses. Moreover, many years of clinical experience have not suggested that hydralazine use is associated with human cancer.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
The HYDRALAZINE HCl 25 KIARA tablets contain the following inactive ingredients: 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).

The HYDRALAZINE HCl 50 KIARA tablets contain the following inactive ingredients: colloidal anhydrous silica, magnesium stearate, maize starch, methylhydroxybenzoate (preservative), povidone K30, talc and the colourant opadry red OY-35003.

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
36 months when packed in polypropylene securitainers and amber glass bottles.
24 months when packed in PVC blisters.
Keep well closed. Store at or below 25 °C and protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

6.4 Special precautions for storage
This medicine does not require any special storage conditions.

6.5 Nature and contents of container
HYDRALAZINE HCl 25 KIARA: Amber glass bottles, securitainers and blister strips of 30, 56, 84, 100 or 500 tablets.
HYDRALAZINE HCl 50 KIARA: Amber glass bottles of 30, 100 or 500 tablets.
Securitainers, sealed aluminium bags and blister strips of 30, 56, 84, 100 or 500 tablets.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park
1619
South Africa

8. Registration numbers
HYDRALAZINE HCl 25 KIARA: Q/7.1.3/269
HYDRALAZINE HCl 50 KIARA: Q/7.1.3/270

9. Date of FIRST AUTHORISATION:
HYDRALAZINE HCl 25 KIARA (tablets): 11 May 1984
HYDRALAZINE HCl 50 KIARA (tablets): 11 May 1984

10. DATE OF REVISION OF TEXT
18 March 2021

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: C02DB02 - Hydrazinophthalazine derivatives

Name and address of manufacturer:
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
Kempton Park, 1619 South Africa

03/21/HYDRAZ-008
V1(10/11/2020)
51009975

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.**

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 overdosage 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 you 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
South Africa

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

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS: S3

HYDRALAZINE HCl 25 KIARA (Tablette)
Hidralasienhidrochloried. Bevat Suiker (Sukrose)
HYDRALAZINE HCl 50 KIARA (Tablette)
Hidralasienhidrochloried. Suikervry

Lees die hele blaadjie sorgvuldig voordat u begin om HYDRALAZINE HCl KIARA-tablette te neem.
- **Hou hierdie blaadjie. U mag nodig hê om dit weer te lees.**
- **Indien u verdere vrae het, vra asseblief u dokter of apteker.**
- **HYDRALAZINE HCl KIARA is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag hulle skaad, selfs al is hulle simptome dieselfde as u simptome.**

1. Wat HYDRALAZINE HCl KIARA is en waarvoor dit gebruik word
Hidralasien behoort aan die algemene klas medisyne wat antihipertensiewe middels genoem word. Dit word gebruik om verskeie vorms van hoë bloeddruk (hipertensie) te behandel. HYDRALAZINE HCl KIARA mag ook vir ander toestande, soos deur u dokter bepaal, gebruik word.

2. Wat u nodig het om te weet voordat u HYDRALAZINE HCl KIARA neem
Moenie HYDRALAZINE HCl KIARA neem nie:
- Indien u hipersensitief (allergies) vir hidralasienhidrochloried of enige van die ander bestanddele van HYDRALAZINE HCl KIARA (gelys in afdeling 6) is.
- Indien u 'n buitensporige harttempo, wat ook tagikardie genoem word, het.
- Indien u swanger is of 'n baba borsvoed.

Waarskuwings en voorsorgmaatreëls:
Tref spesiale sorg met HYDRALAZINE HCl KIARA:
Lig u dokter of apteker in voordat u hierdie medisyne neem:
- Indien u onlangs 'n hartaanval (miokardiale infarksie) gehad het.
- Indien u 'n hart- of bloedvatsiekte het.
- Indien u 'n beroerte gehad het – verlaging van die bloeddruk mag probleme wat uit hierdie toestand voortspruit, erger maak.
- Indien u lewer- of nierfunksie ingekort is.

Ander medisyne en HYDRALAZINE HCl KIARA:
Lig altyd u professionele gesondheidsorgwerker in indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele geneesmiddels in).

Lig u dokter, apteker of ander professionele gesondheidsorgwerker in indien u enige van die volgende medisyne neem:
- Ander medisyne om u hoë bloeddruk te behandel.
- Anti-inflammatoriese middels (NSAIMs).
- Antidepressante (trisiklies, bv. amitriptilien, of monoamienoksidase-inhibeerders, bv. fenelsien, iproniasied, isokarboksasied, nialamied en tranielsipromien).

HYDRALAZINE HCl KIARA met kos en drank:
Die tablette moet heel met 'n glas water gesluk word. Moenie die tablette verkrummel of kou nie. Hierdie medikasie moet met maaltye geneem word.

Swangerkap en Borsvoeding:
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat u hierdie medisyne neem. Moenie HYDRALAZINE HCl KIARA gebruik as u swanger is nie. Hidralasien word in borsmelk uitgeskei. Moeders wie hierdie medisyne neem en wie se wens dit is om te borsvoed, moet dit met hulle dokter bespreek.

Bestuur en die gebruik van masjiene:
HYDRALAZINE HCl KIARA mag veroorsaak dat sommige mense duiselig raak of hoofpyne het. Moenie bestuur of masjiene bedryf voordat u nie weet hoe hierdie medisyne u beïnvloed nie.

HYDRALAZINE HCl KIARA bevat sukrose:
HYDRALAZINE HCl 25 KIARA bevat sukrosekristalle wat 'n effek op die beheer van u bloedsuiker mag hê indien u diabetes mellitus het.

3. Hoe om HYDRALAZINE HCl KIARA te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem HYDRALAZINE HCl KIARA altyd presies soos wat u dokter u opdrag gegee het. Kontak u dokter of apteker as u nie seker is nie.
Dit word aanbeveel dat u hierdie tablette met maaltye neem.

Die gewone dosis vir volwassenes is:
25 tot 75 mg hidralasienhidrochloried daagliks in verdeelde dosisse.
U dokter of professionele gesondheidsorgwerker mag besluit om die dosis oor 'n periode van 2 weke tot 'n maksimum van 200 mg daagliks te vermeerder.

U dokter sal u inlig hoe lank u behandeling met HYDRALAZINE HCl KIARA sal duur. Moenie behandeling vroeg staak nie, want dit kan u huidige toestand vererger.
Indien u die indruk het dat die effek van HYDRALAZINE HCl KIARA te sterk of te swak is, lig u dokter of apteker in.

Indien u meer HYDRALAZINE HCl KIARA neem as wat u moes:
In die geval van 'n oordosering, mag u hoofpyne, duiseligheid, naarheid, braking, vinnige hartklop of waterige oë ervaar. Kontak u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie blaadjie en enige oorblywende tablette saam met u sodat die dokter weet wat u geneem het.

Indien u vergeet om HYDRALAZINE HCl KIARA te neem:
Indien u 'n dosis oorgeslaan het, neem dit so gou as wat u onthou. Indien dit amper tyd vir u volgende dosis is, slaan die vergete dosis oor en gaan voort om die tablet of tablette op die gewone tyd te neem. Moenie 'n dubbele dosis neem om op maak vir die vergete individuele dosisse nie.

4. Moontlike newe-effekte
HYDRALAZINE HCl KIARA kan newe-effekte hê. Die volgende newe-effekte is gemeld:

Nie alle newe-effekte wat vir HYDRALAZINE HCl KIARA gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige effekte ervaar terwyl u HYDRALAZINE HCl KIARA neem, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgverskaffer vir advies.

Kontak u dokter so gou as moontlik indien enige van die volgende newe-effekte voorkom:
Die volgende newe-effekte is minder dikwels gemeld:
- Blase, uitslag of jeuk van die vel.
- Borskaspyn en maagpyn.
- Algemene gevoel van ongemak, siekte of swakheid.
- Swakheid in die hande of voete.
- Swelling van die voete, laer bene of limfnodes.
- Bloedafwykings (abnormaliteite in bloed wanneer bloed getoets word).
- Hoë koors.
- Hallusinasies.
- Hartaanval.

U mag ander newe-effekte ervaar wat gewoonlik nie mediese aandag benodig nie. Raadpleeg egter u dokter indien enige van die volgende newe effekte voortduur of lastig is.
Die volgende newe-effekte is dikwels gemeld:
- Diarree.
- Vinnige hartklop.
- Hoofpyn.
- Naarheid of braking.
- Verlies van sensasie.
- Afwyking van die perifere senuwees.

Die volgende newe-effekte is minder dikwels gemeld:
- Duiseligheid.
- Rooiheid of blosing van die gesig.
- Toeneus.
- Waterige oë.
- Moegheid.
- Gewrigs- en spierpyne.
- Depressie.
- Agitasie.
- Angs.
- Geel oë.
- Lewer- en nierprobleme.

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, lig asseblief u dokter of apteker in.
Aanmelding van newe-effekte
Indien u newe-effekte kry, gesels met u dokter, apteker of verpleegster. U kan newe-effekte ook aan die SARGP via die "**6.04 Nadelige Middelreaksie-Aanmeldingsvorm**" rapporteer; dit kan aanlyn onder die SARGP se publikasies by https://www.sahpra.org.za/Publications/Index/8 gevind word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van HYDRALAZINE HCl KIARA te voorsien.

5. Hoe om HYDRALAZINE HCl KIARA te berg
Hou goed toe. Berg teen of benede 25 °C. Beskerm die medisyne teen lig.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Moenie die tablette na die vervaldatum wat op die houer, stulpstrook of etiket gedruk is, gebruik nie.
Besorg alle ongebruikte medisyne aan u apteker terug.
Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat HYDRALAZINE HCl KIARA bevat
HYDRALAZINE HCl 25 KIARA
Die aktiewe bestanddeel is hidralasienhidrochloried. Die ander bestanddele is kopolimere van pirrolidoon & vinielasetaat, kolloïdale silikoondioksied, hidroksipropielmetielsellulose, magnesiumstearaat, mieliestysel, mikrokristallyne sellulose, povidoon-K30, poliëtileenglikol, sukrosekristalle, talk en die kleurstowwe titaandioksied (CI 77891) en verspreide geel (15093).
HYDRALAZINE HCl 25 KIARA-tablette bevat suiker (22,95 mg sukrosekristalle).

HYDRALAZINE HCl 50 KIARA
Die aktiewe bestanddeel is hidralasienhidrochloried. Die ander bestanddele is kolloïdale anhidriese silika, magnesiumstearaat, mieliestysel, metielhidroksibensoaat (preserveermiddel), povidoon-K30, talk en die HYDRALAZINE HCl 50 KIARA-tablette is suikervry.

Waarna HYDRALAZINE HCl lyk en die inhoud van die pakkie
HYDRALAZINE HCl 25 KIARA: Blink, bleekgeel, ronde, bikonvekse, suikerbedekte tablette.
HYDRALAZINE HCl 50 KIARA: Ronde, bikonvekse, pienk, filmbedekte tablette.

HYDRALAZINE HCl 25 KIARA tablette word verpak in amberkleurige glasbottels, sekuriteitsbewaarders en stulpstroke wat 30, 56, 84, 100 of 500 tablette bevat.
HYDRALAZINE HCl 50 KIARA tablette word verpak in amberkleurige glasbottels wat 30, 100 of 500 tablette bevat. Hierdie tablette word ook verpak in sekuriteitsbewaarders, geseëlde aluminiumsakke en stulpstroke wat 30, 56, 84, 100 of 500 tablette bevat.

Houer van die Sertifikaat van Registrasie
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
Kempton Park 1619
South Africa

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