SCHEDULING STATUS: S3

1. NAME OF MEDICINE
INDAPAMIDE 2,5 KIARA (film-coated tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each INDAPAMIDE 2,5 KIARA film-coated tablet contains 2,5 mg indapamide as the hemihydrate.
Contains sugar (lactose 50 mg).
For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM
White, biconvex, film-coated tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
INDAPAMIDE 2,5 KIARA is indicated in the management of mild to moderate hypertension.

4.2 Posology and method of administration
Adults: 1 tablet per day taken in the morning with breakfast. Higher doses are not recommended since the diuretic effect may become apparent without appreciable additional antihypertensive effect.

Further reduction in blood pressure may be obtained by using indapamide in conjunction with other antihypertensives.

4.3 Contraindications
- Hypersensitivity to indapamide, sulphonamide-derived medicines or any of the other ingredients (see Section 6.1 *List of excipients*).
- Severe hepatic insufficiency.
- Safety in pregnancy has not been established.
- Safety in children has not been established.

4.4 Special warnings and precautions for use
Use with caution in patients with impaired hepatic function as the risk of hepatic encephalopathy may be increased. Patients with hepatic cirrhosis are particularly susceptible to hypokalaemia.

INDAPAMIDE 2,5 KIARA should be used with caution in patients with renal impairment since it can further reduce renal function. It should not be used in patients with severe renal impairment (creatinine clearance less than 30 ml/min).

Attacks of gout may be precipitated in susceptible patients.

INDAPAMIDE 2,5 KIARA may cause hyperglycaemia and aggravate or unmask diabetes mellitus. Blood-glucose concentrations should be monitored in patients taking antidiabetic agents, since requirements may change.

INDAPAMIDE 2,5 KIARA should not be given to patients with Addison's disease.

All patients should be observed for signs of fluid and electrolyte imbalance, especially in the presence of vomiting or during parenteral fluid therapy. Hyponatraemia may occur in patients with severe congestive heart failure who are very oedematous, particularly with large doses in conjunction with restricted salt in the diet. INDAPAMIDE 2,5 KIARA should not be given to patients with existing hypercalcaemia. Elderly patients are particularly susceptible to electrolyte imbalance.

Systemic lupus erythematosus may be exacerbated or activated in susceptible patients.

Lactose intolerance
INDAPAMIDE 2,5 KIARA contains lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take INDAPAMIDE 2,5 KIARA.

4.5 Interactions with other medicines and other forms of interaction
INDAPAMIDE 2,5 KIARA may enhance the toxicity of digitalis glycosides by depleting serum-potassium concentrations. The neuromuscular blocking action of competitive muscle relaxants, such as tubocurarine, may be enhanced.

The effect of antihypertensive agents may be enhanced. Postural hypotension may be enhanced by concomitant ingestion of alcohol, barbiturates, or opioids.

The potassium-depleting effect may be enhanced by corticosteroids, corticotrophin or carbenoxolone.

INDAPAMIDE 2,5 KIARA should not be administered with lithium since this may lead to toxic blood concentrations of lithium.

4.6 Pregnancy and lactation
Safety in pregnancy and breastfeeding has not been established (see Section 4.3 *Contraindications*).

4.7 Effects on the ability to drive or use machinery
The effects on the ability to drive or use machinery have not been investigated.

4.8 Undesirable effects
INDAPAMIDE 2,5 KIARA may provoke hyperglycaemia and glycosuria in diabetic and other susceptible patients. It may cause hyperuricaemia and precipitate attacks of gout in some patients.

Administration of INDAPAMIDE 2,5 KIARA may be associated with electrolyte imbalances including hypochloraemic alkalosis, hyponatraemia and hypokalaemia. The urinary excretion of calcium is reduced, sometimes resulting in hypercalcaemia. Hypomagnesaemia has also occurred. Adverse changes in plasma lipids have been noted but their clinical significance is unclear.

Signs of electrolyte imbalance include dry mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pain and cramps, seizures, oliguria and gastrointestinal disturbances.

Other side-effects include anorexia, gastric irritation, nausea, vomiting, constipation, diarrhoea, headache, dizziness, photosensitivity reactions, postural hypotension, paraesthesia, impotence and yellow vision. Hypersensitivity reactions include skin rashes, pulmonary oedema and pneumonitis. Cholestatic jaundice, pancreatitis and blood dyscrasias including thrombocytopenia, and, more rarely, granulocytopenia, leukopenia and aplastic and haemolytic anaemia have been reported.

4.9 Overdose
Skin rashes, dizziness, nausea, epigastric pain, weakness, photosensitivity and paraesthesia.
Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification:
A 7.1 Hypotensives
ATC Code: C03BA11 - Sulphonamides, plain

Indapamide is an antihypertensive agent with diuretic properties. It is an indole derivative of chlorosulphonamide which shares many chemical, pharmacodynamic and therapeutic similarities with other sulphonamide diuretics.

5.2 Pharmacokinetic properties
Indapamide is rapidly and completely absorbed from the gastrointestinal tract. Elimination is biphasic with a terminal half-life of 14 to 18 hours. It is extensively metabolised and only about 5 % is excreted unchanged.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Croscarmellose sodium, lactose DC, magnesium stearate, methocel E5 premium, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate and titanium dioxide.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store at or below 25 °C in a dry place.

6.5 Nature and contents of container
30, 300 or 600 tablets in white opaque securitainers, clear plastic/silver aluminium blisters or amber glass containers.
30 tablets in sealed aluminium bags.

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

8. REGISTRATION NUMBER:
Z/7.1/203

9. DATE OF FIRST AUTHORISATION
11 October 1993

10. DATE OF REVISION OF THE TEXT
23 June 2021

Additional country(ies) registration details:

Country	Product name	Scheduling status (or Category of distribution)	Registration number
Botswana	INDAPAMIDE 2,5 KIARA	S2	B9309120
Namibia	INDAPAMIDE 2,5 KIARA	NS2	05/7.1/0090

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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

INDAPAMIDE 2,5 KIARA (film-coated tablets)
Indapamide as the hemihydrate
Contains sugar (lactose 50 mg)

Read all of this leaflet carefully before you start taking INDAPAMIDE 2,5 KIARA film-coated tablets.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, or other health care provider.
- INDAPAMIDE 2,5 KIARA has 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 INDAPAMIDE 2,5 KIARA is and what is it used for
Each INDAPAMIDE 2,5 KIARA film-coated tablet contains indapamide hemihydrate equivalent to 2,5 mg indapamide.
INDAPAMIDE 2,5 KIARA is indicated in the management of mild to moderate hypertension.
Each INDAPAMIDE 2,5 KIARA tablet contains sugar (lactose 50 mg).

2. What you need to know before you take INDAPAMIDE 2,5 KIARA
Do not take INDAPAMIDE 2,5 KIARA
- If you are hypersensitive (allergic) to indapamide, sulphonamide-derived medicines or any of the other ingredients (see Section 6 *Contents of the pack and other information*).
- If you suffer from liver impairment.
- If you are pregnant or breastfeeding.

These tablets should not be given to children.

Warnings and precautions
Take special care/Special care should be taken with INDAPAMIDE 2,5 KIARA:
Tell your doctor:
- If you suffer from heart problems.
- If you have low sodium blood levels or are on a salt-restricted diet.
- If you have an elevated calcium concentration in your blood (hypercalcaemia).
- If you suffer from kidney or liver disease.
- If you have a history of gout attacks.
- If you suffer from raised blood sugar (diabetes).
- If you suffer from a disease called Addison's disease (brown pigmentation of the skin and mucous membranes).
- If you suffer from a disease called systemic lupus erythematosus (patchy skin rash).

Elderly patients are more susceptible to electrolyte imbalances.

If you are taking these tablets on a long-term basis, your doctor may want to carry out a number of tests from time to time. This is quite usual and nothing to worry about.

Other medicines and INDAPAMIDE 2,5 KIARA
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently using:
- Heart medication, e.g., digitalis glycosides and amiodarone.
- Other high blood pressure medication (to ensure that your blood pressure does not fall too low).
- Corticosteroids, corticotrophin, or carbenoxolone.
- Lithium.
- Any diuretic (tablets that increase the amount of water excreted from the body). Diuretics are usually prescribed for high blood pressure.

Pregnancy and breastfeeding
INDAPAMIDE 2,5 KIARA should not be used if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care professional for advice.

INDAPAMIDE 2,5 KIARA contains lactose
INDAPAMIDE 2,5 KIARA contains an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking INDAPAMIDE 2,5 KIARA.

3. How to take INDAPAMIDE 2,5 KIARA
Do not share medicines prescribed for you with any other person. Always take INDAPAMIDE 2,5 KIARA exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

***Adults*:**
The usual dose is 1 tablet per day taken in the morning with breakfast. Higher doses are not recommended since the diuretic effect may become apparent without appreciable additional antihypertensive effect. Your doctor will instruct you on the correct dose for your specific condition.
If you have the impression that the effect of INDAPAMIDE 2,5 KIARA is too strong or too weak, talk to your doctor or pharmacist.

If you take more INDAPAMIDE 2,5 KIARA than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take INDAPAMIDE 2,5 KIARA
If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

4. Possible side effects
INDAPAMIDE 2,5 KIARA can have side effects. Not all side effects reported for INDAPAMIDE 2,5 KIARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INDAPAMIDE 2,5 KIARA, please consult your healthcare provider for advice.

An increase in the blood glucose and presence of glucose in the urine have been reported in diabetic patients.

Gout attacks can be precipitated with the use of INDAPAMIDE 2,5 KIARA.

Dry mouth, increased thirst, irregular heartbeat, mood or mental changes, muscle cramps or pain, gastrointestinal disturbances, seizures, unusual tiredness or weakness and a weak pulse can occur due to electrolyte imbalances.

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The following side-effects may be experienced:
- Nausea, vomiting, constipation, anorexia, diarrhoea and gastric irritation.
- Dizziness when getting up and headache.
- Increased sensitivity of the skin to sunlight and a tingling sensation of the skin.
- Yellowing of your skin and yellow vision.
- Sleeping disturbances.
- Allergic reactions that include skin rashes, difficulty in breathing and itching skin.

5. How to store INDAPAMIDE 2,5 KIARA
- Store at or below 25 °C in a dry place.
- Store in the original container.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not store in the bathroom.
- Do not use the tablets after the expiry date printed on the blisters and containers. Decomposed products may be toxic.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What INDAPAMIDE 2,5 KIARA contains
- The active substance is indapamide hemihydrate.
- The other inactive ingredients: croscarmellose sodium, lactose DC, magnesium stearate, methocel E5 premium, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate and titanium dioxide.

What INDAPAMIDE 2,5 KIARA looks like and contents of the pack
White, biconvex, film-coated tablets.
30, 300 or 600 tablets in white opaque securitainers, clear plastic/silver aluminium blisters or amber glass containers.
30 tablets in sealed aluminium bags.

Holder of the Certificate of Registration
Kiara Health (Pty) Ltd
72 Steel Road, Spartan,
Kempton Park, 1619

This leaflet was last revised in
23 June 2021

Registration Number
Z/7.1/203

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS: S3

INDAPAMIDE 2,5 KIARA (filmbedekte tablette)
Indapamied as die hemihidraat
Bevat suiker (laktose 50 mg)

Lees die hele blaadjie sorgvuldig voordat u begin om INDAPAMIDE 2,5 KIARA filmbedekte tablette te neem.
- Hou hierdie blaadjie. U mag nodig kry om dit weer te lees.
- Indien u enige verdere vrae het, vra asseblief u dokter, apteker of ander gesondheidsorgverskaffer.
- INDAPAMIDE 2,5 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 INDAPAMIDE 2,5 KIARA is en waarvoor dit gebruik word
Elke INDAPAMIDE 2,5 KIARA filmbedekte tablet bevat indapamiedhemihidraat gelykstaande aan 2,5 mg indapamied.
INDAPAMIDE 2,5 KIARA is aangedui vir die behandeling van geringe tot matige hipertensie.
Elke INDAPAMIDE 2,5 KIARA tablet bevat suiker (laktose 50 mg).

2. Wat u nodig het om te weet voordat u INDAPAMIDE 2,5 KIARA neem
Moenie INDAPAMIDE 2,5 KIARA neem nie
- Indien u hipersensitief (allergies) vir indapamied, sulfonamiedafgeleide medisyne of enige van die ander bestanddele is (sien Afdeling 6 *Inhoud van die pakkie en ander inligting*).
- Indien u aan lewerinkorting ly.
- Indien u swanger is of borsvoed.

Hierdie tablette moenie aan kinders gegee word nie.

Waarskuwings en spesiale voorsorgmaatreëls
Tref spesiale sorg/Spesiale sorg moet met INDAPAMIDE 2,5 KIARA getref word:
Lig u dokter in:
- Indien u aan hartkwale ly.
- Indien u lae bloedvlakke van natrium het of op 'n soutbeperkte dieet is.
- Indien 'n verhoogde kalsiumkonsentrasie in u bloed het (hiperkalsemie).
- Indien u aan 'n nier- of lewersiekte ly.
- Indien u geskiedenis van jigaanvalle het.
- Indien u verhoogde bloedsuiker (diabetes) het.
- Indien u aan 'n siekte genaamd Addison se siekte (bruin pigmentasie van die vel en slymvliesmembrane) ly.
- Indien u aan 'n siekte genaamd sistemiese lupus eritematose (kollerige veluitslag) ly.

Bejaarde pasiënte is meer vatbaar vir elektrolietsteurings.

Indien u hierdie tablette op 'n langtermyn grondslag neem, mag u dokter van tyd-tot-tyd 'n aantal toetse wil laat doen. Dit is normaal en niks om oor bekommerd te wees nie.

Ander medisyne en INDAPAMIDE 2,5 KIARA
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle aanvullende of tradisionele geneesmiddels in).

Lig u dokter of apteker in indien u tans die volgende gebruik:
- Hartmedisyne, bv. digitalisglikosiede en amiodaroon.
- Ander medisyne vir hoë bloeddruk (om seker te maak dat u bloeddruk nie te laag daal nie).
- Kortikosteroïede, kortikotropien of karbenoksoloon.
- Litium.
- Enige diuretikum (tablette wat die hoeveelheid water wat deur die liggaam uitgeskei word vermeerder). Diuretikums word gewoonlik vir hoë bloeddruk voorgeskryf.

Swangerskap en borsvoeding
INDAPAMIDE 2,5 KIARA moenie gebruik word indien u swanger is of u baba borsvoed nie. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

INDAPAMIDE 2,5 KIARA bevat laktose
INDAPAMIDE 2,5 KIARA bevat 'n bestanddeel genaamd laktose (melksuiker). Indien u erge laktose-intoleransie, galaktose-intoleransie of glukose-galaktose-wanabsorpsie het, lig u dokter in voordat u INDAPAMIDE 2,5 KIARA neem.

3. Hoe om INDAPAMIDE 2,5 KIARA te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem INDAPAMIDE 2,5 KIARA altyd presies soos wat u dokter u opdrag gegee het. U moet u dokter kontak indien u onseker is.

***Volwassenes*:**
Die gewone dosis is 1 tablet per dag wat in die oggend met ontbyt geneem word. Hoër dosisse word nie aanbeveel nie aangesien die diuretiese effek te voorskyn mag tree sonder 'n merkbare bykomende antihipertensiewe effek.
U dokter sal u touwys maak oor die korrekte dosis vir u spesifieke toestand.
Indien u die indruk het dat die effek van INDAPAMIDE 2,5 KIARA te sterk of te swak is, gesels met u dokter of apteker.

Indien u meer INDAPAMIDE 2,5 KIARA neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, soek hulp by die naaste hospitaal of gifsentrum.

Indien u vergeet om INDAPAMIDE 2,5 KIARA te neem
Indien u vergeet het om 'n dosis te neem, drink dit sodra u onthou. Moenie 'n dubbele of groter dosis neem om op te maak vir die vergete individuele dosisse nie. Gaan voort om die volgende tablet op die gewone tyd te neem.

Indien u sukkel om te onhou wanneer om u medisyne te gebruik, vra u apteker vir 'n paar wenke.

4. Moontlike newe-effekte
INDAPAMIDE 2,5 KIARA kan newe-effekte hê.
Nie alle newe-effekte wat vir INDAPAMIDE 2,5 KIARA gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige gevolge ervaar terwyl u INDAPAMIDE 2,5 KIARA neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

'n Styging in bloedglukose en die teenwoordigheid van glukose in die urine is in diabetiese pasiënte gerapporteer.

Jigaanvalle kan met die gebruik van INDAPAMIDE 2,5 KIARA uitgelok word.

Droë mond, verhoogde dors, onreëlmatige hartklop, gemoed- of geestesveranderinge, spierkrampe of -pyn, gastro-intestinale versteurings, stuipe, ongewone moegheid of swakheid en 'n swak pols kan vanweë elektrolietwanbalanse voorkom.

Die volgende newe-effekte kan ervaar word:
- Naarheid, braking, hardlywigheid, anoreksie, diarree en gastriese irritasie.
- Duiseligheid wanneer regop gekom word en hoofpyn.
- Verhoogde sensitiwiteit van die vel vir sonlig en 'n tintelende sensasie van die vel.
- Geelverkleuring van die vel en geel visie.
- Slaapsteurings.
- Allergiese reaksies wat veluitslae, moeisame asemhaling en jeukende vel insluit.

5. Hoe om INDAPAMIDE 2,5 KIARA te berg
- Berg teen of benede 25 °C in 'n droë plek.
- Bewaar in die oorspronklike houer.
- HOU ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
- Moenie in die badkamer berg nie.
- Moenie die tablette gebruik na die vervaldatum wat op die stulpstroke en houers gedruk is nie. Ontbinde produkte kan toksies wees.
- Besorg alle ongebruikte medisyne aan u apteker terug.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat INDAPAMIDE 2,5 KIARA bevat
- Die aktiewe bestanddeel is indapamiedhemihidraat.
- Die ander onaktiewe bestanddele: natriumkroskarmellose, laktose DC, magnesiumstearaat, metosel E5 premium, mikrokristallyne sellulose, poliëtileenglikol, natriumstyselglikolaat en titaandioksied.

Waarna INDAPAMIDE 2,5 KIARA lyk en inhoud van die pakkie
Wit, bikonvekse, filmbedekte tablette.
30, 300 of 600 tablette in wit, ondeursigtige sekuriteitsbewaarders, helder plastiek-/silwer aluminiumstulpstroke of amber glashouers.
30 tablette in geseëlde aluminiumsakkies.

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

Hierdie blaadjie was laas hersien op
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