

## 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.

#### **What is in this leaflet**

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

#### **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.

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. 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

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Kempton Park  
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**Registration Number**

Z/7.1/203

**Additional country(ies) registration details:**

<b>Country</b>	<b>Product name</b>	<b>Scheduling status (or Category of distribution)</b>	<b>Registration number</b>
<b>Botswana</b>	Indapamide 2,5 Kiara	S2	B9309120
<b>Namibia</b>	Indapamide 2,5 Kiara	NS2	05/7.1/0090

**Name and address of manufacturer:**

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