Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Kerendia 10 mg
Kerendia 20 mg

film-coated tablets

Active ingredient

Kerendia 10 mg: Each tablet contains 10 mg finerenone.

Kerendia 20 mg: Each tablet contains 20 mg finerenone.

Inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Kerendia is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.

Therapeutic group: diuretics, aldosterone antagonists.

Kerendia contains the active substance finerenone. Finerenone works by blocking the action of certain hormones (mineralocorticoids) that can damage the kidneys, heart and blood vessels.

Chronic kidney disease is a long-term condition. The kidneys keep getting worse at removing waste and fluids from the blood.

Type 2 diabetes develops when the body cannot maintain normal blood sugar levels. The body does not produce enough of the hormone insulin or cannot use the insulin properly. This leads to a high level of sugar in the blood.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You are taking medicines that belong to the group of strong CYP3A4 inhibitors, for example
  - **itraconazole** or **ketoconazole** (to treat fungal infections)
  - **ritonavir**, **nelfinavir**, or **cobicistat** (to treat HIV infection)
  - **clarithromycin**, **telithromycin** (to treat bacterial infections)
  - **nefazodone** (to treat depression).
- You suffer from **adrenal insufficiency.**
- You are breastfeeding.
- You suffer from severe hepatic impairment (Child Pugh C)

Special warnings about using this medicine

Before using Kerendia, tell your doctor if:

- You have ever been told that you had a high level of potassium in your blood.
- You have impairment of kidney function.
- You have moderate or severe liver problems. Do not use Kerendia in patients with severe hepatic impairment.

Children and adolescents

This medicine is not intended for children and adolescents under 18 years of age.

There is no information about the safety and effectiveness of using this medicine in children and adolescents under 18 years of age.

Tests and follow-up

Blood tests

These tests check the potassium level and kidney function.

Based on the results of the blood tests, your doctor decides whether you can start to take Kerendia. After 4 weeks of taking Kerendia, you will have more blood tests.

Your doctor may perform blood tests at other times, for example, while you are taking certain medicines.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Your doctor will tell you which medicines you can take. Your doctor may need to perform blood tests to make sure.

You must not take medicines that belong to the group of strong CYP3A4 inhibitors while taking Kerendia (see section 2 "Do not use this medicine if").

Talk to your doctor or pharmacist if you are taking other medicines while taking Kerendia, especially if you take:

- medicines that can cause a rise in blood potassium levels, for example:
  - **amiloride** or **triamterene** (to remove excess water from the body in the urine)
  - **eplerenone**, **esaxerenone**, **spironolactone**, or **canrenone** (medicines similar to finerenone)
  - **trimethoprim**, or a **combination of trimethoprim and sulfamethoxazole** (to treat bacterial infections)
  - **potassium supplements**, including certain salt substitutes

  Monitor the potassium levels in the blood more frequently in these patients.
- medicines that belong to the group of mild or moderate CYP3A4 inhibitors, for example:
  - **erythromycin** (to treat bacterial infections)
  - **verapamil** (to treat high blood pressure, chest pain, and fast heartbeat)
  - **fluvoxamine** (to treat depression and obsessive-compulsive disorder)

  You may have more side effects if you use these medications together with Kerendia.
- medicines that belong to the group of strong and moderate CYP3A4 activators, for example:
  - **rifampicin** (to treat bacterial infections)
  - **carbamazepine**, **phenytoin**, or **phenobarbital** (to treat epilepsy)
  - **St. John´s Wort** (*Hypericum perforatum*) (a herbal medicine to treat depression)
  - **efavirenz** (to treat HIV infection)

  Concomitant use may cause a decrease in the effectiveness of Kerendia.

Using this medicine with food and drink

Do not eat grapefruit or drink grapefruit juice as long as you take Kerendia.

If you consume grapefruit or grapefruit juice, your finerenone blood level may be too high. **You may have more side effects** (the side effects are listed in section 4).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There is not enough data on the use of Kerendia during pregnancy and the influence of the treatment on the unborn baby and the mother.

Breastfeeding

Do not breastfeed while taking this medicine and for one day after treatment ends. It may harm your baby.

Driving and using machines

This medicine is not expected to affect your ability to drive or use machines.

Important information about some of this medicine's ingredients

Kerendia contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Kerendia contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended and the maximum daily dose of this medicine is 1 tablet of 20 mg.

- Always take **1 tablet once daily**. Each tablet contains 10 mg or 20 mg finerenone.
- The **starting dose** depends on how well your kidneys work. To check this, your doctor will perform a blood test. The results will help your doctor to decide if you can start with **1 tablet of 20 mg or 10 mg** once daily.
- **After 4 weeks,** your doctor will perform a blood test again. Your doctor will decide on the correct dose for you. The dose might be **1 tablet of 20 mg or 10 mg** once daily.

  Your doctor may also tell you to interrupt or stop taking Kerendia.

Your doctor may decide on **changes in your treatment** after **performing blood tests**. See "Tests and follow-up" in section 2 for more information.

How to take this medicine

Kerendia is taken by mouth. Take Kerendia at the same time every day. This will make it easier for you to remember.

Swallow the tablet whole.

- You can take it with a glass of water.
- You can take it with or without food.
- Do not take it with grapefruit juice or grapefruit. See "Using this medicine with food and drink" in section 2 for more information.

If you cannot swallow the tablet whole, you can crush it.

- Mix it with water or soft foods, such as apple sauce.
- Take it right away.

If you have accidentally taken a higher dose

Talk to your doctor or pharmacist if you think you have taken too much of this medicine. The most common manifestation of overdose is hyperkalemia (see section 4 "Side effects"). In such case, your doctor will initiate the standard treatment.

If you forget to take the medicine

If you forget to take your tablet at the regular time on that day, take the tablet as soon as you notice it on that day.

If you **miss a day,** take the next tablet on the next day, at the regular time.

Do not take 2 tablets to make up for a forgotten tablet.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Consult your doctor before stopping treatment.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Kerendia may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects that your doctor may see in blood test results

Very common side effects – effects that affect more than one in ten users

- high potassium level (hyperkalemia)

  Possible signs of high potassium level in the blood may include weakness or tiredness, nausea, numbness in the hands and lips, muscle cramps, decreased pulse rate.

Common side effects – effects that affect up to one in ten users

- low sodium level (hyponatremia)

  Possible signs of low sodium level in the blood may include nausea, tiredness, headache, confusion, muscle weakness, spasms or cramps.
- decrease in the efficacy of blood filtration by the kidneys (decreased glomerular filtration rate).
- slight increase in blood levels of uric acid
- low blood pressure (hypotension).

  Possible signs of low blood pressure may include dizziness, lightheadedness and fainting.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/blister tray/bottle. The expiry date refers to the last day of that month.

Storage conditions

This medicine does not require any special storage conditions. Storage at room temperature is recommended.

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

- Tablet core:

  microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hypromellose 5 cP, magnesium stearate, sodium laurilsulfate, purified water.
- Tablet coat:

  hypromellose 5 cP, titanium dioxide, talc, ferric oxide red (in Kerendia 10 mg film-coated tablets only), ferric oxide yellow (in Kerendia 20 mg film-coated tablets only), purified water.

What the medicine looks like and contents of the pack:

Kerendia 10 mg film-coated tablets are pink and oval-oblong, marked with '10' on one side and 'FI' on the other side.

Kerendia 20 mg film-coated tablets are light yellow and oval-oblong, marked with '20' on one side and 'FI' on the other side.

Kerendia is available in carton boxes containing

- 14, 28 or 98 film-coated tablets packed in aluminum blisters.
- 100 * 1 film-coated tablets packed in perforated unit dose blisters.

  Each perforated transparent unit dose blister contains 10 film-coated tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

Manufacturer's name and address:

Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Germany

Approved in January 2023, according to MOH guidelines

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Kerendia 10 mg: 171-38-37226-99

Kerendia 20 mg: 171-39-37227-99