Package leaflet: Information for the patient
Kerendia 10 mg film-coated tablets
Kerendia 20 mg film-coated tablets
finerenone

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kerendia is and what it is used for
Kerendia contains the active substance finerenone. Finerenone works by blocking the action of certain hormones (mineralocorticoids) that can damage your kidneys and heart.
Kerendia is used for the **treatment of adults with chronic kidney disease** (with abnormal presence of the protein albumin in the urine) associated with type 2 diabetes.
Chronic kidney disease is a long-term condition. Your kidneys keep getting worse at removing waste and fluids from your blood.
Type 2 diabetes is when your body cannot keep your blood sugar levels normal. Your body does not produce enough of the hormone insulin or cannot use the insulin properly. This leads to a high level of sugar in your blood.

2. What you need to know before you take Kerendia
Do not take Kerendia if you
- are **allergic** to finerenone or any of the other ingredients of this medicine (listed in section 6).
- 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).
- have **Addison's disease** (when your body does not produce enough of the hormones 'cortisol' and 'aldosterone').

Warnings and precautions
Talk to your doctor or pharmacist before taking Kerendia if you have
- ever been told you had a high level of potassium in your blood.

- severe loss of kidney function or kidney failure.
- moderate or severe liver problems.
- mild, moderate or severe heart failure. This is when your heart does not pump blood as well as it should. It does not pump enough blood out of the heart in one beat.

Blood tests
These tests **check your potassium level and how your kidneys are working**.
Using the results of your 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 test your blood at other times, for example while you are taking certain medicines.

Children and adolescents
Do not give this medicine to children and adolescents under 18 years because it is not known yet whether it is safe and effective in this age group.

Other medicines and Kerendia
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will tell you which medicines you can take. Your doctor may need to test your blood 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 take Kerendia…").

Talk to your doctor or pharmacist **if you are taking** other medicines while taking Kerendia, especially:
- if you take for example
  - **amiloride** or **triamterene** (to remove excess water from your 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 some salt substitutes

  or if you take other medicines that may increase the level of potassium in your blood. These medicines may be unsafe for you.
- if you take 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')
  - **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)

  or if you take other medicines that belong to the same groups of medicines as the ones listed above (certain 'CYP3A4 inhibitors' and 'inducers'). You may have more side effects, or Kerendia may not work as expected.
- if you take several other **blood pressure lowering medicines**. Your doctor may need to watch your blood pressure.

Kerendia with food and drink
Do not eat grapefruit or drink grapefruit juice as long as you take Kerendia.
If you do, you may get too much finerenone in your blood. **You may have more side effects** (possible side effects are listed in section 4).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You should **not take** this medicine during pregnancy **unless** your doctor states it is clearly necessary. There might be a risk to your unborn baby. Your doctor will discuss that with you.
You should **use reliable birth control** if you are able to become pregnant. Your doctor will explain to you what type of birth control you can use.
Breast-feeding
You should **not breast-feed** while taking this medicine. It may harm your baby.

Driving and using machines
Kerendia has no effect on your ability to drive or use machines.

Kerendia contains lactose
If you have been told by your doctor that you have an intolerance to some 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 take Kerendia

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much you have to take
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 test your blood. The results 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 test your blood again. Your doctor will decide on the correct dose for you. This 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 testing your blood**. See "Blood tests" 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 makes 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 "Kerendia 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 take more Kerendia than you should
Talk to your doctor or pharmacist if you think you have taken too much of this medicine.

If you forget to take Kerendia
If you forget to take your tablet at **your regular time that day**

- take the tablet as soon as you notice it that day.

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

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

If you stop taking Kerendia
Only stop taking Kerendia if your doctor has told you. Your doctor may decide this after testing your blood.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects that your doctor may see in your blood test results
very common (may affect more than 1 in 10 people)
- high potassium level (hyperkalaemia)
  Possible signs of high potassium level in the blood may include weakness or tiredness, feeling sick (nausea), numbness in the hands and lips, muscle cramps, decreased pulse rate.

common (may affect up to 1 in 10 people)
- low sodium level (hyponatraemia)
  Possible signs of low sodium level in the blood may include feeling sick (nausea), tiredness, headache, confusion; muscle weakness, spasms or cramps.
- decrease in how well the kidneys filter blood (glomerular filtration rate decreased)
- high uric acid level (hyperuricaemia)

uncommon (may affect up to 1 in 100 people)
- decrease in a protein (haemoglobin) that is found in your red blood cells.

Other side effects
common (may affect up to 1 in 10 people)
- low blood pressure (hypotension)
  Possible signs of low blood pressure may include dizziness, lightheadedness, fainting.
- itching (pruritus)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):

United Arab Emirates (UAE):
Pharmacovigilance & Medical Device section
Tel: 80011111 / +971 42301000
Email: pv@mohap.gov.ae
Website: www.mohap.gov.ae
P.O.Box 1853 Dubai

Egypt:
Egyptian Pharmaceutical Vigilance Centre
Hotline: 15301
Email: pv.followup@edaegypt.gov.eg
Website: www.edaegypt.gov.eg

Jordan:
Tel: +962-6-5632000
JFDA email : jpc@jfda.jo
JFDA website: www.jfda.jo
http://primaryreporting.who-umc.org/JO

Kuwait:
Drug &Food Control, Ministry of Health
Tel.: +965-24811532
Fax: +965-24811507
Email : Adr_reporting@moh.gov.kw
Website: http://eservices.moh.gov.kw/SPCMS/DrugCmp.aspx

Oman:
Tel: +968 - 2444 1999
Fax: +968 - 24602287
Email: pharma-vigil@moh.gov.om
Website: www.moh.gov.om

Other Countries:
Please contact the relevant competent authority.

5. How to store Kerendia

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister, bottle label and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 30°C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kerendia contains

- The active substance is finerenone.
  Each tablet of Kerendia **10 mg film-coated tablets** contains 10 mg finerenone.
  Each tablet of Kerendia **20 mg film-coated tablets** contains 20 mg finerenone.
- The other ingredients are:
  - Tablet core: microcrystalline cellulose, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, sodium laurilsulfate. See “Kerendia contains lactose” and “Kerendia contains sodium” in section 2 for more information.
  - Tablet coat: hypromellose 2910, titanium dioxide, talc,
    iron oxide red (E 172, in Kerendia **10 mg film-coated tablets** only),
    iron oxide yellow (E 172, in Kerendia **20 mg film-coated tablets** only).

What Kerendia looks like and contents of the pack
Kerendia **10 mg film-coated tablets** (tablets) are pink and oval-oblong, marked ‘10’ on one side and ‘FI’ on the other side.
Kerendia **20 mg film-coated tablets** (tablets) are yellow and oval-oblong, marked ‘20’ on one side and ‘FI’ on the other side.

Kerendia is available in cartons containing 14, 28 or 98 film-coated tablets. Each calendarised transparent blister contains 14 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bayer AG
51368 Leverkusen Germany

Manufacturer
Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen Germany

This leaflet was last revised in February 2023.

This is a medicinal product

- A medicine is a product which affects your health and can harm you if taken contrary to directions.
- Keep strictly to your doctor's instructions, the instructions for use and the instructions of the pharmacist who sold you this medicine. Your doctor and pharmacist are experts on medicine and its benefits and risks.
- Do not stop taking this medicine before the end of the prescribed course of treatment.
- Do not use this medicine on another occasion without consulting your doctor.

Keep medicines out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists