Kerendia® 10 mg film-coated tablets
Kerendia® 20 mg film-coated tablets

(finerenone)

UK5281951P99-A1.0

▼ 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.

This product is called Kerendia 10 mg film-coated tablets and Kerendia 20 mg film-coated tablets but will be referred to as Kerendia throughout the leaflet.

What is in this leaflet

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

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.

What Kerendia is used for
Kerendia 10 mg or 20 mg tablets are used for the **treatment of adults with chronic kidney disease** (stage 3 and 4 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.

Kerendia 10 mg, 20 mg or 40 mg tablets are used for the treatment of adults with symptomatic chronic heart failure (with left ventricular ejection fraction of 40% or higher).
Chronic heart failure is a long-term condition. Your heart does not work as well as it should.
The most common symptoms of heart failure are feeling breathless, feeling tired, and ankle swelling. Kerendia helps protect your heart from getting worse and improves your symptoms.
It can lower the need to go to hospital and can help some patients to live longer.

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.

<u>Blood tests</u>
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.

While taking Kerendia, some patients with **heart failure** may experience a decrease in how well their kidneys are working. Your doctor will test your blood on a regular basis to check how well your kidneys are working, and more often if you are **65 years or older** or you have reduced kidney function.

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.
- ► if you take medicines that belong to certain groups of medicines (sensitive 'CYP3A4' or 'CYP2C8' substrates) along with Kerendia 40 mg tablets. Some of these medicines may not work as expected. Your doctor should review your other medicines and decide on possible changes.

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.

<u>Pregnancy</u>
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.

<u>Breast-feeding</u>
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

Your doctor will decide how much of this medicine you need to take.
The dose may change as your treatment continues.
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
If you have **chronic kidney disease**, the recommended and the **maximum daily dose** of this medicine is **1 tablet** of **20 mg**.
If you have **heart failure**, the **maximum daily dose** of this medicine is **1 tablet** of **40 mg**.
The dose recommended for you by your doctor may be lower.
- ► Always take **1 tablet once daily**. Each tablet contains 10 mg, 20 mg or 40 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 1**0 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 **40 mg**, **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.
In adults with **chronic kidney disease** associated with type 2 diabetes, the following side effects were seen:

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.
- ► changes in results that are used to check how well your kidneys are working (blood creatinine increased/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)

In adults with **symptomatic chronic heart failure** (with left ventricular ejection fraction of 40% or higher), the following side effects were seen:

Side effects that your doctor may see in your blood test results

Common (may affect up to 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.
► 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.
► changes in results that are used to check how well your kidneys are working (blood creatinine increased/ glomerular filtration rate decreased).
► high uric acid level (hyperuricaemia)

Other side effects

Common (may affect up to 1 in 10 people)
► reduced kidney function (renal impairment) or sudden inability of the kidneys to work properly (acute kidney injury)
► low blood pressure (hypotension)
Possible signs of low blood pressure may include dizziness, lightheadedness, fainting.
► diarrhoea
► constipation

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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.

This medicine does not require any special storage conditions.

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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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 (E 460), croscarmellose sodium, hypromellose 2910 (E 464), lactose monohydrate, magnesium stearate (E 470b), sodium laurilsulfate (E 487). See “Kerendia contains lactose” and “Kerendia contains sodium” in section 2 for more information.
- Tablet coat: hypromellose 2910 (E 464), titanium dioxide (E 171), talc (E 553b), iron oxide red (E 172, in Kerendia **10 mg film-coated tablets**), iron oxide yellow (E 172, in Kerendia **20 mg film-coated tablets**).

What Kerendia looks like and contents of the pack
Kerendia **10 mg film-coated tablets** (tablets) are pink and oval-oblong, 10 mm long and 5 mm wide, marked ‘10’ on one side and ‘FI’ on the other side.

Kerendia **20 mg film-coated tablets** (tablets) are pale yellow and oval-oblong, 10 mm long and a 5 mm wide, marked ‘20’ on one side and ‘FI’ on the other side.

Kerendia is available in cartons containing
- 28 film-coated tablets.
Each calendarised transparent blister contains 14 film-coated tablets.

Manufacturers
Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen
Germany

or

Bayer HealthCare Manufacturing S.r.l.
Via delle Groane, 126
20024 Garbagnate Milanese
Italy

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

Kerendia 10 mg film-coated tablets
PL 45763/1951
PL 45763/1953

Kerendia 20 mg film-coated tablets
PL 45763/1952
PL 45763/1954

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For any information about this medicine, please contact the local representative of the Product Licence Holder:
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