Patient Information Leaflet

SCHEDULING STATUS: S4

FIRIALTA 10 mg film-coated tablets
FIRIALTA 20 mg film-coated tablets
finerenone
Contains sugar
Lactose monohydrate

Read all of this leaflet carefully before you start taking FIRIALTA
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- FIRIALTA 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 FIRIALTA is and what it is used for
2. What you need to know before you take FIRIALTA
3. How to take FIRIALTA
4. Possible side effects
5. How to store FIRIALTA
6. Contents of the pack and other information

1. What FIRIALTA is and what it is used for

FIRIALTA contains the active substance finerenone. Finerenone works by blocking the action of certain hormones (mineralocorticoids) that can damage your kidneys and heart.

FIRIALTA 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 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 FIRIALTA

Do not take FIRIALTA**:**
- if you are **hypersensitive (allergic)** to finerenone or any of the other ingredients of FIRIALTA listed in section 6,
- if 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).

- if you have **Addison's disease** (when your body does not produce enough of the hormones 'cortisol' and 'aldosterone').

If any of the above applies to you, **talk to your doctor first** and do not take this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking FIRIALTA,
- if you have ever been told you had a high level of potassium in your blood.
- if you have severe loss of kidney function or kidney failure
- if you have moderate or severe liver problems.
- if you have 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 FIRIALTA.
After 4 weeks of taking FIRIALTA, 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 FIRIALTA to children and adolescents aged under 18 years because it is not known yet whether it is safe and effective in this age group.

Other medicines and FIRIALTA

Always tell your healthcare professional if you are taking, have recently taken or might take any other medicines (including complementary or traditional medicines), 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 FIRIALTA may not work as expected.

if you take several other **blood pressure lowering medicines**. Your doctor may need to watch your blood pressure.

FIRIALTA with food and drink
Do not eat grapefruit or drink grapefruit juice as long as you take FIRIALTA.
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 breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking FIRIALTA.

Pregnancy
You should **not take** FIRIALTA during pregnancy. 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.

Breastfeeding
You should **not breast-feed** while taking FIRIALTA. It may harm your baby.

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

FIRIALTA contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FIRIALTA.

FIRIALTA contains sodium
FIRIALTA contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take FIRIALTA

Do not share medicines prescribed for you with any other person.

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

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 FIRIALTA.

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
FIRIALTA is taken by mouth. Take FIRIALTA 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 "FIRIALTA 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 and take it right away.

If you take more FIRIALTA than you should
If you take more FIRIALTA than you should, you may get side effects listed in section 4.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take FIRIALTA
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 a double dose to make up for a forgotten tablet.

If you stop taking FIRIALTA
Only stop taking FIRIALTA 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

FIRIALTA can have side effects.

Not all side effects reported for FIRIALTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FIRIALTA, please consult your doctor, pharmacist, or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing. This could be a sign of a severe allergic reaction.

Tell your doctor if you notice any of the following:

Most frequent (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.

Frequent (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).
- low blood pressure (hypotension)
    - Possible signs of low blood pressure may include dizziness, lightheadedness, fainting.
- itching (pruritus)
- high uric acid level (hyperuricaemia)

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (https://www.safetrack-public.bayer.com). By reporting side effects, you can help provide more information on the safety of FIRIALTA.

5. How to store FIRIALTA

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 carton and on each blister after "EXP". The expiry date refers to the last day of that month.

FIRIALTA does not require any special storage conditions.

Do not dispose of unused medicines in drains or sewerage system (e.g. toilets). 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 FIRIALTA contains

- The active substance is finerenone. Each film-coated tablet contains 10 mg, or 20 mg finerenone.
- The other ingredients are:
  Tablet core: Microcrystalline cellulose, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, sodium laurilsulfate (see section 2 “FIRIALTA contains lactose” and “FIRIALTA contains sodium”).
  Film-coat: Hypromellose 2910, talc, titanium dioxide (E 171), iron oxide red (E 172) (FIRIALTA 10 mg only), iron oxide yellow (E 172) (FIRIALTA 20 mg only).

What FIRIALTA looks like and contents of the pack

FIRIALTA 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.

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

FIRIALTA is available in blisters in cartons of 14 or 28 film-coated tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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