

What is in this leaflet

1. What *Firialta* is used for
2. How *Firialta* works
3. Before you use *Firialta*
4. How to use *Firialta*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Firialta*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Firialta* is used for

Chronic kidney disease and type 2 diabetes:

Firialta treats adults with chronic kidney disease associated with type 2 diabetes. Chronic kidney disease is when 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.

Firialta slows the worsening of kidney damage.

Firialta lowers the combined risk of dying from heart or blood vessel disease, having a heart attack, and being hospitalized for heart failure.

Heart failure and LVEF of 40% or higher:

Firialta treats adults with heart failure and LVEF of 40% or higher. Heart failure is when the heart does not pump blood as well as it should. The bottom left side of the heart (the left ventricle) is stiff. The amount of blood it holds or pumps out is lower than normal. LVEF (left ventricular ejection fraction) is a heart function measurement.

Firialta lowers the chance of death from heart or blood vessel disease. It can lower hospital stays and emergency visits for heart failure.

How *Firialta* works

Firialta contains the active substance finerenone. Finerenone is a nonsteroidal 'mineralocorticoid receptor antagonist (MRA)'. It works by blocking hormones that can damage the kidneys and heart.

Before you use *Firialta*

Your doctor decided that you can take Firialta and the dose best for you. For those decisions, your doctor used the results of your blood tests. These tests check your potassium level and how your kidneys are working.

After 4 weeks of taking Firialta, you will have more blood tests. Your doctor will tell you if you will go on taking your dose as before.

Your doctor may test your blood at other times.

- When you must not use it

Do not take *Firialta* and tell your doctor if you

- are taking a 'strong CYP3A4 inhibitor', for example,
 - itraconazole or ketoconazole, to treat infections caused by a fungus or yeast
 - ritonavir, nelfinavir, or cobicistat, to treat HIV infection
 - clarithromycin, to treat bacterial infections
 - telithromycin, to treat pneumonia
 - nefazodone, to treat depression.
- have Addison's disease.

- Before you start to use it

Before taking Firialta, tell your healthcare provider about all your medical conditions, including if you have:

- a high level of potassium in your blood (hyperkalemia) or had that before.
- severe loss of kidney function (severe renal impairment) or kidney failure (end-stage renal disease).
- moderate or severe liver damage (moderate or severe hepatic impairment or Child Pugh B or C).

Pregnancy

Tell your doctor if you are pregnant, think you may be pregnant or plan on becoming pregnant. Firialta should not be taken during pregnancy unless clearly necessary. Your doctor will discuss with you the risk to your unborn baby if you

take Firialta during pregnancy.

If you are female and able to give birth, you should use reliable birth control. Your doctor will explain to you what type of birth control you can use.

Breast-feeding

Tell your doctor if you are breastfeeding or planning to breastfeed. You should not breastfeed while taking Firialta. Firialta may cause harm to your nursing baby.

Fertility

Firialta is not expected to lower the ability to have children (fertility) in men or women.

Children [and adolescents]

Firialta should not be used in pediatric patients. Firialta has not been studied in children under the age of 18 years.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Talk to your doctor before taking *Firialta* if you are taking

- 'moderate or weak CYP3A4 inhibitors', for example,
 - erythromycin, to prevent and treat bacterial infections
 - verapamil, to treat high blood pressure, chest pain, and fast heartbeat
 - amiodarone, to treat irregular heartbeat
 - fluvoxamine, to treat depression and 'obsessive-compulsive disorder (OCD)'

If you take 10mg, 20mg or 40mg Firialta while taking any of these medicines, you may get too much of the active substance, finerenone, in your blood. You may have more side effects.

- 'strong or moderate CYP3A4 inducers', for example,
 - rifampicin, to treat bacterial infections
 - carbamazepine, phenytoin, or phenobarbital, to treat seizures
 - St. John's Wort, to treat depression

Firialta® (finerenone) Film-Coated Tablet 10mg, 20mg

- **efavirenz**, to treat HIV infection

If you take 10mg, 20mg or 40mg Firialta while taking any of these medicines, you may not get enough of the active substance, finerenone, in your blood. Firialta may not work as expected.

- **medicines that may increase the level of potassium in your blood**, for example,

- amiloride or triamterene (water pills or potassium-sparing diuretics) to remove excess water from your body in urine
- eplerenone, esaxerenone, spironolactone or canrenone (MRAs like finerenone)
- **trimethoprim**, or a **combination of trimethoprim and sulfamethoxazole**, to treat bacterial infections
- **potassium supplements**

If you take 10mg, 20mg or 40mg Firialta while taking any of these medicines, you may get too much potassium in your blood (hyperkalemia). This may be unsafe for you.

- **sensitive CYP3A4 or CYP2C8 substrates** that have a small difference between a helpful dose and a harmful dose, for example:

- **cyclosporin** or **tacrolimus** to help prevent the body from attacking a transplanted organ.

If you take 40 mg of Firialta while taking any of these medicines, you may get too much of the active substance of those medicines in your blood. You may have side effects.

Firialta with food and drink

You can take Firialta with or without food.

Do not eat grapefruit or drink grapefruit juice if you take Firialta. If you do, you may get too much finerenone in your blood. You may have more side effects.

Check with your doctor before taking Firialta with a salt substitute. Some salt substitutes contain potassium. If you use it while taking Firialta, you may get too much potassium in your blood (hyperkalemia). This may be unsafe for you.

How to use Firialta

- How much to use

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

Your doctor may tell you to take either 10 mg, 20 mg, or 40 mg once daily, depending on your blood test results.

The maximum amount of Firialta that you can take in one day is:

- 1 tablet of 20 mg once daily if you have chronic kidney disease and type 2 diabetes
- 2 tablets of 20 mg (a total of 40 mg) once daily if you have heart failure and LVEF of 40% or higher

- When to use it

Try to take Firialta at the same time every day. This makes it easier for you to remember.

You can take Firialta with a glass of water. Swallow the tablet whole.

If you cannot swallow the whole tablet, you can crush it. Mix it with water or soft foods, such as applesauce, and take it right away.

- How long to use it

Do not stop taking Firialta or change your dose without talking to your doctor

- If you forget to use it

Do not take an additional dose on the same day to make up for a missed dose.

- If you forget to take Firialta at your regular time that day: Take the tablet as soon as you notice.
- If you miss a day: Take the next tablet on the next day.

- If you use too much (overdose)

Talk to your doctor.

While you are using it

- Things you must do

Always take this medicine exactly as your doctor has told you.

If you have any further questions on using this medicine, ask your doctor or pharmacist.

- Things you must not do

Only stop taking Firialta if your doctor has told you.

Your doctor may decide this after testing your blood.

- Things to be careful of

Driving and using machines

Firialta has no effect on your ability to drive or use machines.

Side Effects

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

Talk to your doctor if you get any side effects, including any possible side effects not listed in this leaflet.

Very common: may affect more than 1 in 10 people

- Hyperkalemia (high potassium level in the blood)

Common: may affect up to 1 in 10 people

- Hyponatremia (low sodium level in the blood)
- Hyperuricemia (high uric acid level in the blood)
- Hypotension (low blood pressure)
- Blood creatinine increased (high creatinine level in the blood) / Glomerular filtration rate decreased (decrease in how well the kidneys filter blood)

Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

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Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Firialta*

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton and on each blister or bottle after “EXP”. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

Firialta 10mg film-coated tablet

Pink, oval-oblong tablet with a length of 10 mm and a width of 5 mm, marked '10' on one side and 'FI' on the other side.

Firialta 20mg film-coated tablet

Yellow, oval-oblong tablet with a length of 10 mm and a width of 5 mm, marked '20' on one side and 'FI' on the other side.

- Ingredients

- Active ingredients

The active substance is finerenone.

Each 10 mg film-coated Firialta tablet contains 10 mg finerenone.

Each 20 mg film-coated Firialta tablet contains 20 mg finerenone.

- Inactive ingredients

Tablet core:

- Cellulose, microcrystalline
- Croscarmellose sodium
- Hypromellose
- Lactose monohydrate
- Magnesium stearate
- Sodium laurilsulfate.

Film coat (10mg):

- Hypromellose
- Talc
- Titanium dioxide
- Ferric oxide red

Film coat (20mg):

- Hypromellose
- Talc
- Titanium dioxide
- Ferric oxide yellow

- MAL number(s):

MAL24046010AZ

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Manufacturer

Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen
Germany

Product Registration Holder

Bayer Co (Malaysia) Sdn Bhd
25-03 & 25-04, Level 25, IMAZIUM
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Selangor Darul Ehsan

Date of revision

22/12/2025

Serial number:

NPRA (R1) 23/023

NPRA (R1/AI1) 08122025/021