ERLEADA® FILM-COATED TABLETS

Apalutamide (60mg)

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What ERLEADA® is used for

ERLEADA® is used to treat adult men patients with prostate cancer that:

- has spread to other parts of the body and still responds to medical or surgical treatments that lower testosterone (also called hormone-sensitive prostate cancer).
- has not spread to other parts of the body and no longer responds to medical or surgical treatment that lowers testosterone (also called castration-resistant prostate cancer).

How ERLEADA® works

ERLEADA® contains the active substance apalutamide. ERLEADA® works by blocking the activity of hormones called androgens (such as testosterone). Androgens can cause the cancer to grow. By blocking the effect of androgens, apalutamide stops prostate cancer from growing and dividing.

Before you use ERLEADA®

- *When you must not use it*

Do not take ERLEADA®

- if you are allergic to apalutamide or any of the other ingredients of this medicine (listed in Product Description)
- if you are a woman who is pregnant or may become pregnant (see the Pregnancy and contraception section below for more information).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Woman, infants, and children

ERLEADA® is not for use in women and children under 18 years of age.

Pregnancy and contraception information for men and women

Information for women

- Erleada must not be taken by women who are pregnant, may become pregnant, or who are breast-feeding. This medicine may harm your unborn baby.

Information for men – follow this advice during treatment and for 3 months after stopping

- If you are having sex with a pregnant woman – use a condom to protect the unborn baby.
- If you are having sex with a woman who can become pregnant - use a condom and another highly effective method of contraception.

Use contraception during treatment and for 3 months after stopping. Talk to your doctor if you have any questions about contraception.

Fertility

ERLEADA® may impair fertility in males.

- *Before you start to use it*

Before you take ERLEADA®, tell your healthcare provider if you:

- have a history of fits or seizures
- are taking any medicines to prevent blood clots (e.g. warfarin, acenocoumarol)
- have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia)
- have ever developed a widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms or DRESS) or a severe skin rash or skin peeling, blistering and/or mouth sores (Stevens Johnson syndrome/toxic epidermal necrolysis or SJS/TEN) after taking ERLEADA® or other related medicines

Falls and broken bones

Falls have been observed in patients taking ERLEADA®. Take extra care to reduce your risk of a fall. Broken bones have been observed in patients taking ERLEADA®.

Heart disease, stroke, or mini-stroke

Blockage of the arteries in the heart or in part of the brain that can lead to death has happened in some people during treatment with ERLEADA®. Your healthcare provider will monitor you for signs and symptoms of heart or brain vessel disorders during your treatment with ERLEADA®. Call your healthcare provider or go to the nearest emergency room right away if you get chest pain or discomfort at rest or with activity, or shortness of breath, or if you get muscle weakness/paralysis in any part of the body, or difficulty in speaking during your treatment with ERLEADA®.

If you are taking any medicines, talk to your doctor or pharmacist to see if they are associated with an increased risk of seizure, bleeding or heart condition.

Severe Cutaneous Adverse Reactions (SCARs)

Severe Cutaneous Adverse Reactions (SCARs), including drug reaction with eosinophilia and systemic symptoms (DRESS) or Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), have been reported with the use of ERLEADA®. DRESS can appear as widespread rash, high body temperature and enlarged lymph nodes. SJS/TEN can appear initially as reddish target like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal. If you develop a serious rash or another of these skin symptoms, stop taking ERLEADA®and contact your doctor or seek medical attention immediately.

Interstitial Lung Disease
Cases of interstitial lung disease (non-infectious inflammation within the lungs that may lead to permanent damage) have been observed in patients taking ERLEADA®, including fatal cases. The symptoms of interstitial lung disease are cough and shortness of breath sometimes with fever which are not caused by physical activity. Seek immediate medical attention, if you experience symptoms that may be signs of interstitial lung disease.

- *Taking other medicines*
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because ERLEADA® can affect the way some other medicines work. Also, some medicines can affect the way ERLEADA® works.

Tell your doctor if you are taking medicines that:
- Lower high fat levels in the blood (e.g. gemfibrozil)
- Treat bacterial infections (e.g. moxifloxacin, clarithromycin)
- Treat fungal infections (e.g. itraconazole, ketoconazole)
- Treat HIV infections (e.g. ritonavir, efavirenz, darunavir)
- Treat anxiety (e.g. midazolam, diazepam)
- Treat epilepsy (e.g. phenytoin, valproic acid)
- Treat gastroesophageal reflux disease (conditions where there is too much acid in the stomach) (e.g. omeprazole)
- Prevent blood clots (e.g. warfarin, clopidogrel, dabigatran etexilate)
- Treat hayfever and allergies (e.g. fexofenadine)
- Lower cholesterol levels (e.g. 'statins' such as rosuvastatin, simvastatin)
- Treat heart conditions or lower blood pressure (e.g. digoxin, felodipine)
- Treat heart rhythm problems (e.g. quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide)
- Treat thyroid conditions (e.g. levothyroxine)
- Treat gout (e.g. colchicine)
- Lower blood glucose (e.g. repaglinide)
- Treat cancer (e.g. lapatinib, methotrexate)
- Treat opioid addiction or pain (e.g. methadone)
- Treat serious mental illness (e.g. haloperidol)

You need to list the names of medicines you take and show the list to your doctor or pharmacist when you start a new medicine. Mention to your doctor that you are taking ERLEADA® if the doctor wants to start you on any new medicine.

How to use ERLEADA®
- *How much to use*
Take ERLEADA® exactly as your healthcare provider tells you.

The recommended dose of ERLEADA® is 240mg (four 60mg tablets) once a day.

If you have severe liver disease, the recommended dose of this medicine is 120 mg (two 60 mg tablets) once a day.

Your healthcare provider may change your dose if needed.

- *When to use it*
Take ERLEADA® with or without food.

Swallow ERLEADA® tablets whole to make sure your full dose is taken. Do not crush or split the tablets.

- *If you cannot swallow this medicine whole, you can:*
Mix with one of the following non fizzy beverages or soft foods; orange juice, green tea, applesauce, drinkable yogurt, or additional water as follows:
  - Place the entire prescribed dose of Erleada in a cup. Do not crush or split the tablets.
  - Add about 20 mL (4 teaspoons) of non fizzy water to make sure that the tablets are completely in water.
  - Wait 2 minutes until the tablets are broken up and spread out, then stir the mixture.
  - Add in 30 mL (6 teaspoons or 2 tablespoons) of one of the following non fizzy beverages or soft foods: orange juice, green tea, applesauce, drinkable yogurt, or additional water and stir the mixture.
  - Swallow the mixture immediately.
  - Rinse the cup with enough water to make sure the whole dose is taken and drink it immediately.
  - Do not save the medicine/food mixture for later use.

Feeding tube: This medicine may also be given through certain feeding tubes. Ask your healthcare provider for specific instructions on how to properly take the tablets through a feeding tube.

- *How long to use it*
Do not stop taking your prescribed dose of ERLEADA® without talking to your healthcare provider first.

Your healthcare provider may do blood tests to check for side effects.

- *If you forget to use it*
If you missed a dose of ERLEADA®, take your normal dose as soon as you remember.

If you forget to take ERLEADA® for the whole day – take your usual dose the following day.

If you forget to take ERLEADA® for more than one day – talk to your doctor straight away.

Do not take a double dose to make up for a forgotten dose.

- *If you use too much (overdose)*
If you accidentally take more than the usual dose, stop taking ERLEADA® and contact your doctor. You may have an increased risk of side effects.

If you have further questions on the use of this medicine, ask your healthcare provider.

While you are using it
- *Things you must do*
Tell all the doctors, dentists and pharmacists treating you that you are taking ERLEADA®.

- *Things you must not do*
  Do not give ERLEADA® to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
  Driving and using machines
  ERLEADA® has no or negligible influence on the ability to drive and use machines. Seizures has been reported in patients taking ERLEADA®. Patients should be advised of this risk in regards to driving or operating machines.

Side effects
Like all medicines, ERLEADA® can cause side effects, although not everybody gets them.

Stop using ERLEADA® and seek medical attention immediately if you notice any of the following symptoms:
- widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms or DRESS)
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

ERLEADA® may cause serious side effects including:

Very common: may affect more than 1 in 10 people
- Falls or fractures (broken bones). Your healthcare provider may monitor you more closely if you are at risk for fractures.

Common: may affect up to 1 in 10 people
- Heart disease, stroke, or mini-stroke. Your healthcare provider will monitor you for signs and symptoms of heart or brain problems during your treatment. Call your healthcare provider or go to the nearest emergency room right away if you get chest pain or discomfort at rest or with activity, or shortness of breath, or if you get muscle weakness/paralysis in any part of the body, or difficulty in speaking during your treatment with ERLEADA®.

Uncommon: may affect up to 1 in 100 people
- Fit or seizure. Your healthcare provider will stop ERLEADA® if you have a seizure during treatment.
- Restless legs syndrome (urges to move the legs to stop painful or odd sensations, often occurring at night).

Not known: frequency cannot be estimated from the available data
- Coughing and shortness of breath, possibly accompanied by fever, that is not brought on by physical activity (inflammation within the lungs, known as interstitial lung disease).

Tell your healthcare provider if you notice any of the serious side effects above.

Side effects include:
Very common (May affect more than 1 in 10 people)
- feeling very tired
- joint pain
- skin rash
- decreased appetite
- high blood pressure
- hot flush
- diarrhoea
- broken bones
- falls
- weight loss

Common (may affect up to 1 in 10 people)
- muscle spasms
- itching
- hair loss
- change in sense of taste
- blood test showing high level of cholesterol in the blood
- blood test showing high level of a type of fat called "triglycerides" in the blood
- heart disease
- stroke or mini-stroke caused by low blood flow to part of the brain
- under-active thyroid which can make you feel more tired and have difficulty getting started in the morning, and blood tests may also show an under-active thyroid
- low level of a type of white blood cell which can make you more likely to get infections (neutropenia)

These are not all the possible side effects of ERLEADA®. Tell your healthcare provider if you have any side effects that bothers you or that does not go away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vacines (AEFI)].

Storage and disposal of ERLEADA®
- *Storage*
  Keep out of the sight and reach of children.

  Do not use this medicine after the expiry date which is stated on the container (blister foils, inner wallet, outer wallet, bottle, and carton) after EXP. The expiry date refers to the last day of the month.

  Store in the original package in order to protect from moisture. Do not store above 30ºC.

- *Disposal*
  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description
- *What it looks like*
  Slightly yellowish to greyish green, oblong-shaped, film-coated (FC) tablets, debossed with "AR 60" on one side.

- *Ingredients*
  - Active ingredient
    Each film-coated tablet of ERLEADA® contains 60mg of apalutamide.

  - Inactive ingredients
    Tablet core
    Colloidal anhydrous silica, croscarmellose sodium,

hydroxypropyl methylcellulose-acetate succinate (HPMC-AS), magnesium stearate, microcrystalline cellulose, microcrystalline cellulose (silicified).

Film-coat
Iron oxide black (E172), iron oxide yellow (E172), macrogol, polyvinyl alcohol (partially hydrolyzed), talc, titanium dioxide (E171).

ERLEADA® contains less than 1 mmol sodium (23 mg) per 240 mg dose (4 tablets), that is to say essentially 'sodium-free'.

- *MAL number*
  MAL20026041ARZ

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