PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ERLEADA® 60 mg film-coated tablets

Apalutamide

Sugar free

Read all of this leaflet carefully before you start using ERLEADA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ERLEADA 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 ERLEADA is and what it is used for

ERLEADA contains the active substance apalutamide and it belongs to a group of medicines called “androgen receptor inhibitors”.

ERLEADA is used to treat your prostate cancer that has:

- spread to other parts of your body and still responds to treatments that lower testosterone.
- not yet spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone.

  ERLEADA is usually used in combination with a medicine called "a gonadotrophin releasing hormone analogue" (GnRH) or without a GnRH, if you have had a bilateral orchiectomy (surgical removal of both testes).

2. What you need to know before you take ERLEADA

Do not take ERLEADA

- if you are hypersensitive (allergic) to apalutamide or any of the other ingredients of ERLEADA.
- if you are a woman, are pregnant or may become pregnant. ERLEADA may harm your unborn baby.
- If you have a history of seizures or epilepsy.

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.

Warnings and precautions

Take special care with ERLEADA and tell your doctor, pharmacist or nurse if you:

- have a history of heart disease, high blood pressure, diabetes, have abnormal amounts of fat or cholesterol in your blood (dyslipidaemia).
- have a history of seizures/epilepsy, brain injury, stroke, or brain tumours (non-cancerous or cancerous).
- have a partner who is pregnant or may become pregnant. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with ERLEADA. If your sexual partner may become pregnant, the partner must use a highly effective contraception/birth control method during and for 3 months after treatment. Talk with your healthcare provider if you have questions about birth control.
- ERLEADA may decrease the function of your thyroid gland. Tell your doctor if you have a history of thyroid gland illness or are taking thyroxin.

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.

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 problems during your treatment with ERLEADA. Call your healthcare provider or go to the nearest casualty 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 not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Children and adolescents

This medicine is not for use in children and adolescents under 18 years of age.

Other medicines and ERLEADA

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should not stop or start any medicine before you talk with your doctor that prescribed ERLEADA.

Tell your doctor if you are taking medicines that:

- treat bacterial infections (e.g. rifampicin, clarithromycin, moxifloxacin),
- treat fungal infections (e.g. itraconazole, ketoconazole),
- treat anxiety (e.g. midazolam, diazepam),
- treat gastroesophageal reflux disease (conditions where there is too much acid in the stomach) (e.g. omeprazole),
- prevent blood clots (e.g. warfarin),
- treat hayfever and allergies (e.g. fexofenadine),
- lower cholesterol levels (e.g. ‘statins’ such as rosuvastatin, simvastatin).

The dose of ERLEADA or any other medicines that you are taking may need to be changed.

ERLEADA with food

ERLEADA can be taken with or without food.

Pregnancy and Breastfeeding

ERLEADA is **not** for use in women and children.

Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with ERLEADA. If your sexual partner can become pregnant, you must use a condom and your female partner a highly effective contraception method during and for 3 months after treatment. Please consult your doctor, pharmacist or other healthcare professional for advice before taking this ERLEADA.

Driving and using machines

You should not drive and use machines until you know how treatment with ERLEADA affects you.

Treatment with ERLEADA is associated with falls and seizures. These may make driving and the use of machines potentially hazardous.

ERLEADA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 240 mg dose (4 tablets).

3. How to take ERLEADA

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

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

The usual dose 240 mg (four tablets) once a day.

Taking ERLEADA

- Take ERLEADA by mouth.
- You can take ERLEADA with or without food.
- Swallow the tablets whole with water.
- Your healthcare provider may change your dose if needed.
- 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.

Your doctor will tell you how long your treatment with ERLEADA will last. Do not stop any treatment unless your doctor tells you to do so. If you have the impression that the effect of ERLEADA is too strong or too weak, tell your doctor or pharmacist.

If you take more ERLEADA than you should

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

If you forget to take ERLEADA

If you miss a dose of ERLEADA, take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ERLEADA

Do not stop taking ERLEADA without checking with your doctor first.

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

4. Possible side effects

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

If any of the following happens, stop taking ERLEADA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Skin rash or itching
- Fit or seizure. You may experience a seizure when taking ERLEADA. Your healthcare provider will stop ERLEADA if you have a seizure during treatment.
- Falls that may cause bone fractures (broken bones). Your healthcare provider may monitor you more closely if you are at risk for fractures.
- 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 problems during your treatment with ERLEADA. Call your healthcare provider or go to the nearest casualty 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.

Other side effects include:

Frequent side effects

- Feeling very tired,
- Weight loss,
- Joint pain,
- Muscle spasms,
- Change in sense of taste,
- Heart disease caused by low blood flow to the heart,
- High blood pressure,
- Hot flash/hot flush,
- Diarrhoea,
- Stroke or mini-stroke caused by low blood flow to part of the brain
- Blood test showing high levels of cholesterol in the blood,
- Blood test showing high level of a type of fat called ‘triglycerides’ in the blood.
- Underworking of your thyroid gland (hypothyroidism).

Less frequent side effects

- Decreased appetite,
- Inflammation within the lungs that may lead to permanent damage (interstitial lung disease),
- Life-threatening rash with blisters and peeling over much of the body (toxic epidermal necrolysis).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/8
By reporting side effects, you can help provide more information on the safety of ERLEADA.

Alternatively, you may report side effects experienced with ERLEADA directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5 How to store ERLEADA

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original outer carton package to protect from light and moisture.
- Do not use this ERLEADA after the expiry date stated on the label / carton. The expiry date refers to the last day of that month.
- ERLEADA does not require any special storage conditions.
- Return all unused ERLEADA to your pharmacist.
- Do not dispose of unused ERLEADA in drains or sewerage systems (e.g. toilets). These measures will help protect the environment.

6 Contents of the pack and other information

What ERLEADA contains

The active substance is apalutamide. Each film-coated tablet contains 60 mg apalutamide.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl methylcellulose-acetate succinate (HPMC-AS), magnesium stearate, microcrystalline cellulose, microcrystalline cellulose (silicified), iron oxide black (E172), iron oxide yellow (E172), polyethylene glycol, polyvinyl alcohol (partially hydrolysed), talc and titanium dioxide (see section 2, “ERLEADA contains sodium”).

What ERLEADA looks like and contents of the pack

ERLEADA 60 mg film-coated tablets are slightly yellowish to greyish green, oblong-shaped tablets with ‘AR 60’ on one side.

ERLEADA is available in an opaque polyvinyl chloride – polychlorotrifluoroethylene (PVC-PCTFE) foil blister with an aluminum push-through foil. Each 30-day carton contains 120 film coated tablets in 5 cardboard wallet packs of 24 film-coated tablets each.

Holder of certificate of registration

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Registration number

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Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.