Package leaflet: Information for the user

Erleada 240 mg film-coated tablets
apalutamide

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.

What is in this leaflet

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

1. What Erleada is and what it is used for

What Erleada is
Erleada is a cancer medicine that contains the active substance ‘apalutamide’.

What Erleada is used for
It is used to treat adult men with prostate cancer that:
- has metastasised 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 metastasised 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 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 cells from growing and dividing.

2. What you need to know before you take Erleada

Do not take Erleada
- if you are allergic to apalutamide or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if:
- you have ever had fits or seizures.
- you are taking any medicines to prevent blood clots (such as warfarin, acenocoumarol).
- you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia).
- you have ever had 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.

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

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 this medicine.

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 this medicine.

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
- muscle weakness/paralysis in any part of the body, or
- difficulty in speaking.

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 this medicine and contact your doctor or seek medical attention immediately.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine. See section 4 ‘Serious side effects’ at the top of section 4 for more information.

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.

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

If a child or young person accidentally takes this medicine:
- go to the hospital straight away
- take this package leaflet with you to show to the emergency doctor.

Other medicines and Erleada
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 other medicines can affect the way Erleada works.

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

You need to list the names of the 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. The dose of Erleada or any other medicines that you are taking may need to be changed.

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.

This medicine may reduce male fertility.

Driving and using machines
Erleada is not likely to affect you being able to drive and use any tools or machines.

The side effects for this medicine include seizures. If you are at higher risk of seizures (see Section 2 'Warnings and precautions'), talk to your doctor.

Erleada contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 240 mg dose (1 tablet), that is to say essentially 'sodium-free'.

3. How to take Erleada

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

Your doctor may also prescribe other medicines while you are taking Erleada.

How much to take
The recommended dose of this medicine is 240 mg (one tablet) once a day.

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

Taking Erleada
- Take this medicine by mouth.
- You can take this medicine with food or between meals.
- Swallow the tablet whole to make sure your full dose is taken. Do not crush or split the tablet.

If you cannot swallow the tablet whole
- 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 whole tablet in a cup. Do not crush or split the tablet.
    - Add about 10 mL (2 teaspoons) of non-fizzy water to make sure that the tablet is completely in water.
    - Wait 2 minutes until the tablet is 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 tablet through a feeding tube.

If you take more Erleada than you should
If you take more than you should, stop taking this medicine and contact your doctor. You may have an increased risk of side effects.

If you forget to take Erleada
- If you forget to take this medicine, take your usual dose as soon as you remember on the same day.
- If you forget to take this medicine for the whole day - take your usual dose the following day.
- If you forget to take this medicine 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 stop taking Erleada
Do not stop taking this medicine 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

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

Serious side effects
Stop taking 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).

Tell your doctor straight away if you notice any of the following serious side effects – your doctor may stop treatment:

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 this medicine 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 right away if you notice any of the serious side effects above.

Side effects include
Tell your healthcare provider if you notice any of the following side effects:

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).

Uncommon (may affect up to 1 in 100 people):
- seizures/fits
- eruption of the skin or mucous membranes (lichenoid eruption).

Not known (frequency cannot be estimated from the available data):
- abnormal heart tracing on an ECG (electrocardiogram)
- 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, which can be preceded by fever and flu-like symptoms. These serious skin rashes can be potentially life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- very low level of a type of white blood cell which can make you more likely to get infections (agranulocytosis).

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

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: https://yellowcard.mhra.gov.uk 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 Erleada

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 container (blister foils, inner wallet, outer wallet, bottle, and carton) after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. This medicine does not require any special temperature 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.

6. Contents of the pack and other information

What Erleada contains

- The active substance is apalutamide. Each film-coated tablet contains 240 mg of apalutamide.
- The other ingredients of the tablet core are colloidal anhydrous silica, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, and silicified microcrystalline cellulose. The film-coating contains glycerol monocaprylocaprate, iron oxide black (E172), poly (vinyl alcohol), talc, titanium dioxide (E171), and macrogol poly (vinyl alcohol) grafted copolymer (see section 2, Erleada contains sodium).

What Erleada looks like and contents of the pack
Erleada film-coated tablets are bluish grey to grey, oval-shaped, film-coated tablets (21 mm long x 10 mm wide), with “E240” written on one side.

The tablets may be supplied either in a bottle or in a wallet pack. Not all pack sizes may be marketed.

Bottle
The tablets are supplied in a plastic bottle with a child-resistant closure. Each bottle contains 30 tablets and a total of 2 g of desiccant. Each carton contains one bottle. Store in the original package. Do not swallow or discard desiccant.

28-day carton
Each 28-day carton contains 28 film-coated tablets in 2 cardboard wallet packs of 14 film-coated tablets each.

30-day carton
Each 30-day carton contains 30 film-coated tablets in 3 cardboard wallet packs of 10 film-coated tablets each.

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