Package leaflet: Information for the user

Erleada 60 mg film-coated tablets
apalutamide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

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

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).

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).
- 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 (e.g. warfarin, acenocoumarol)
- you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia).

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 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.

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

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 Erleada:
- 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.

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 infection (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 illnesses (e.g. 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. Erleada 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.

Erleada may reduce male fertility.

Driving and using machines
This medicine is not likely to affect you being able to drive and use any tools or machines. The side effects for Erleada 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 (4 tablets), 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.

How much to take
The recommended dose is 240 mg (four 60 mg tablets) once a day.

Taking Erleada
- Take this medicine by mouth.
- You can take Erleada with food or between meals.
- Swallow the tablets whole.

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

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

If you forget to take Erleada
If you forget to take Erleada, take your usual 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 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

Like all medicines, this medicine 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:
- 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 (toxic epidermal necrolysis).

Serious side effects
Tell your doctor straight away if you notice any of the following serious side effects – your doctor may stop treatment:
- fit or seizure – this is uncommon (may affect up to 1 in 100 people). Your healthcare provider will stop Erleada if you have a seizure during treatment.
- falls or fractures (broken bones) – these are very common (may affect more than 1 in 10 people). Your healthcare provider may monitor you more closely if you are at risk for fractures.
- heart disease, stroke, or mini-stroke – this is common (may affect up to 1 in 10 people). 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.

Tell your healthcare provider right away 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.

Uncommon (may affect up to 1 in 100 people):
- seizures/fits

Not known (frequency cannot be estimated from the available data):
- abnormal heart tracing on an ECG (electrocardiogram)
- life-threatening rash with blisters and peeling over much of the body (toxic epidermal necrolysis).

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: www.mhra.gov.uk/yellowcard 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 60 mg of apalutamide.
- The other ingredients of the tablet core are colloidal anhydrous silica, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, and silicified microcrystalline cellulose. The film-coating contains iron oxide black (E172), iron oxide yellow (E172), macrogol, polyvinyl alcohol (partially hydrolysed), talc, and titanium dioxide (E171).

What Erleada looks like and contents of the pack
Erleada film-coated tablets are slightly yellowish to greyish green, oblong-shaped, film-coated tablets (16.7 mm long x 8.7 mm wide), with “AR 60” 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 120 tablets and a total of 6 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 112 film-coated tablets in 4 cardboard wallet packs of 28 film-coated tablets each.

30-day carton
Each 30-day carton contains 120 film-coated tablets in 5 cardboard wallet packs of 24 film-coated tablets each.

Marketing Authorisation Holder

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