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Erleada (*apalutamide*)

An overview of Erleada and why it is authorised in the EU

What is Erleada and what is it used for?

Erleada is a cancer medicine used to treat men with cancer of the prostate (a gland of the male reproductive system).

It is used when the cancer is not responding to treatments that lower testosterone levels (castration resistant) and is at high risk of spreading to other parts of the body. It is also used when the cancer has spread to other parts of the body (metastatic) but responds to treatment that lowers testosterone levels (hormone sensitive). Erleada is used in combination with a treatment called androgen deprivation therapy.

Erleada contains the active substance apalutamide.

How is Erleada used?

Erleada is available as tablets (60 mg) to be taken by mouth. The recommended dose is 4 tablets (240 mg) a day. Treatment may have to be temporarily interrupted if the patient experiences intolerable side effects.

Erleada can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the treatment of prostate cancer. For more information about using Erleada, see the package leaflet or contact your doctor or pharmacist.

How does Erleada work?

The active substance in Erleada, apalutamide, works by blocking the action of testosterone and other male hormones known as androgens. It does this by blocking the receptors (targets) to which these hormones attach. Because prostate cancer cells need testosterone and other male hormones to survive and grow, by blocking the effects of these hormones, apalutamide slows down the growth of the cancer.

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What benefits of Erleada have been shown in studies?

In a main study involving 1,207 patients with non-metastatic, castration-resistant prostate cancer, Erleada was shown to be more effective than placebo (a dummy treatment) at prolonging the time patients lived without the disease spreading to other parts of the body: patients on Erleada lived on average for 41 months without the disease spreading, compared with 16 months for patients taking placebo. Both Erleada and placebo were given with a treatment called androgen deprivation therapy.

In another main study involving 1,052 patients with metastatic, hormone-sensitive prostate cancer, Erleada in combination with androgen deprivation therapy was effective at delaying worsening of the disease: after 2 years, the disease did not get worse in 68% of patients receiving Erleada and androgen deprivation therapy compared with 48% of those who received placebo with androgen deprivation therapy. After 2 years, 82% of patients given Erleada were alive compared with 74% of those in the placebo group.

What are the risks associated with Erleada?

The most common side effects with Erleada (which may affect more than 1 in 10 people) are tiredness, skin rash, hypertension (high blood pressure), hot flushes, , joint pain, diarrhoea, falls, fractures (broken bones) and weight loss. For the full list of side effects of Erleada, see the package leaflet.

Erleada must not be used by women who are pregnant or may become pregnant. For the full list of restrictions, see the package leaflet.

Why is Erleada authorised in the EU?

Erleada is effective at delaying the spread of prostate cancer that is not responding to testosterone-lowering treatments and is at high risk of spreading to other parts of the body. It is also effective at delaying the worsening of the disease in patients whose cancer has spread to other parts of the body and is sensitive to hormones. Although more data are needed on its effects on prolonging patients' life, the benefits seen so far are considered important.

Regarding its safety, the side effects with Erleada were considered manageable. The European Medicines Agency therefore decided that Erleada's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Erleada?

In order to further evaluate the effectiveness of Erleada, the company that markets the medicine has to submit the final results of the main study, including data on the effects of the medicine on prolonging patients' life.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Erleada have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Erleada are continuously monitored. Side effects reported with Erleada are carefully evaluated and any necessary action taken to protect patients.

Other information about Erleada

Erleada received a marketing authorisation valid throughout the EU on 14 January 2019.

Further information on Erleada can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/erleada.

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