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Enzalutamide Viatris (*enzalutamide*)

An overview of Enzalutamide Viatris and why it is authorised in the EU

What is Enzalutamide Viatris and what is it used for?

Enzalutamide Viatris is a cancer medicine used to treat men with prostate cancer. It can be used:

- together with hormone therapy (treatment to lower production of testosterone) when the cancer is metastatic (has spread to other parts of the body) and is hormone-sensitive (depending on a hormone, such as testosterone, to grow);
- for metastatic cancer that is castration-resistant (worsens despite treatment to lower production of testosterone or after surgical removal of the testes) when either:
    - treatment with docetaxel (another cancer medicine) has not worked or no longer works, or
    - hormone therapy has not worked, and the patient has either no symptoms or mild symptoms and does not yet require chemotherapy (another type of cancer treatment);
- for castration-resistant prostate cancer that is not metastatic but is at high risk of doing so;
- on its own or together with hormone therapy, for hormone-sensitive prostate cancer that is not metastatic, if there are rapidly rising levels of prostate-specific antigen (PSA; a protein made by the prostate gland) indicating that the cancer may have returned, in men who cannot receive salvage radiotherapy (radiation treatment given after the cancer has not responded to other treatments).

Enzalutamide Viatris contains the active substance enzalutamide and is a 'generic medicine'. This means that Enzalutamide Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Enzalutamide Viatris is Xtandi. For more information on generic medicines, see the question-and-answer document here.

How is Enzalutamide Viatris used?

Enzalutamide Viatris can only be obtained with a prescription and treatment should be started and monitored by a doctor who has experience in treating prostate cancer.

Enzalutamide Viatris is available as tablets, taken once daily at about the same time each day. The doctor may reduce the dose or interrupt treatment if a patient gets certain side effects.

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For more information about using Enzalutamide Viatris, see the package leaflet or contact your doctor or pharmacist.

How does Enzalutamide Viatris work?

The active substance in Enzalutamide Viatris, enzalutamide, works by blocking the action of the hormone testosterone and other hormones known as androgens. Enzalutamide does this by blocking the receptors (targets) to which these hormones attach. Because prostate cancer needs testosterone and other androgens to survive and grow, by blocking the effects of these hormones, enzalutamide slows down the growth of the prostate cancer.

How has Enzalutamide Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Xtandi, and do not need to be repeated for Enzalutamide Viatris.

As for every medicine, the company provided studies on the quality of Enzalutamide Viatris. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Enzalutamide Viatris?

Because Enzalutamide Viatris is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Enzalutamide Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Enzalutamide Viatris has been shown to have comparable quality and to be bioequivalent to Xtandi. Therefore, the Agency's view was that, as for Xtandi the benefits of Enzalutamide Viatris outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Enzalutamide Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Xtandi also apply to Enzalutamide Viatris where appropriate.

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

Other information about Enzalutamide Viatris

Enzalutamide Viatris received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Enzalutamide Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/enzalutamide-viatris. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 08-2024.