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Enzalutamide Accordpharma (*enzalutamide*)

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

What is Enzalutamide Accordpharma and what is it used for?

Enzalutamide Accordpharma 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 (a cancer that depends 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) and when either:
  - treatment with docetaxel (a 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 has not yet spread 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. It is used in men who cannot receive salvage radiotherapy (radiation treatment given after the cancer has not responded to other treatments) and when there are rapidly rising levels of prostate-specific antigen (PSA; a protein made by the prostate gland). This indicates that the cancer may have returned.

Enzalutamide Accordpharma contains the active substance enzalutamide and is a 'generic' and a 'hybrid' medicine. This means that it is similar to a 'reference medicine' containing the same active substance, but there are certain differences between the two. The reference medicine is available as tablets and capsules, while Enzalutamide Accordpharma is only available as tablets. In addition, as well as being available at the same strengths as the reference medicine tablets (40 and 80 mg), Enzalutamide Accordpharma is also available at an additional higher strength (160 mg). The reference medicine for Enzalutamide Accordpharma is Xtandi.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How is Enzalutamide Accordpharma used?

Enzalutamide Accordpharma 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 Accordpharma is available as tablets to be 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.

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

How does Enzalutamide Accordpharma work?

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

How has Enzalutamide Accordpharma been studied?

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

As for every medicine, the company provided studies on the quality of Enzalutamide Accordpharma. 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 Accordpharma?

Because Enzalutamide Accordpharma 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 Accordpharma authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Enzalutamide Accordpharma 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 Accordpharma 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 Accordpharma?

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

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

Other information about Enzalutamide Accordpharma

Enzalutamide Accordpharma received a marketing authorisation valid throughout the EU on 9 January 2026.

Further information on Enzalutamide Accordpharma can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/enzalutamide-accordpharma.

This overview was last updated in 9 January 2026.