



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Xtandi (*enzalutamide*)

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

### What is Xtandi and what is it used for?

Xtandi 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 is not metastatic (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 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).

The medicine contains the active substance enzalutamide.

### How is Xtandi used?

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

Xtandi is available as capsules and 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.

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

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## **How does Xtandi work?**

The active substance in Xtandi, 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.

## **What benefits of Xtandi have been shown in studies?**

### **Metastatic prostate cancer**

Xtandi has been compared with placebo (a dummy treatment) in a main study involving 1,199 patients with metastatic, castration-resistant prostate cancer who were previously treated with docetaxel. In this study, Xtandi was more effective than placebo at prolonging patients' lives: on average, patients treated with Xtandi lived for 18 months, compared with 14 months for patients given placebo.

Xtandi has also been compared with placebo in a second main study involving 1,717 patients with metastatic, castration-resistant prostate cancer in whom hormone therapy had failed, but who had no symptoms or mild symptoms and had not previously been treated with chemotherapy. Patients treated with Xtandi lived on average for around 32 months compared with 30 months for patients given placebo. In addition, patients treated with Xtandi lived for longer without their disease showing signs of worsening in a radiographic scan: 20 months compared with 5 months for patients treated with placebo.

A third main study showed that Xtandi was more effective than placebo in 1,150 patients with hormone-sensitive metastatic prostate cancer who either also received hormone therapy to lower testosterone or had their testes surgically removed. The disease got worse more slowly in patients taking Xtandi compared with those given placebo. The average period before the disease got worse in those given placebo was 19 months but the average for those taking Xtandi could not be calculated because the disease had not got worse in many patients during the follow up period.

### **Non-metastatic prostate cancer**

Xtandi has been compared with placebo in a study involving 1,401 patients with castration-resistant prostate cancer at high risk of becoming metastatic. Patients treated with Xtandi lived for an average of 37 months without their disease becoming metastatic compared with 15 months on placebo.

Another study involved 1,068 previously treated patients with rapidly rising levels of PSA whose prostate cancer had not spread and was hormone sensitive. In this study patients given Xtandi with leuprolide (a medicine that blocks the production or action of male hormones) or Xtandi on its own lived longer without their disease becoming metastatic compared to those treated with placebo given with leuprolide. Within the study patients' blood levels of PSA were monitored; if their PSA levels were undetectable after 36 weeks, treatment was paused and restarted if their PSA levels began to increase again. After around 61 months, the cancer had spread, or the patient died, in around 13 % of patients given Xtandi with leuprolide (45 out of 355) and around 18% of patients given Xtandi on its own (63 out of 355) compared to around 26% (92 out of 358) of patients given placebo with leuprolide.

## **What are the risks associated with Xtandi?**

For the full list of side effects and restrictions of Xtandi, see the package leaflet.

The most common side effects with Xtandi (which may affect more than 1 in 10 people) include weakness, tiredness, falls, fractures (broken bones), hot flushes and hypertension (high blood pressure). Other important side effects include ischaemic heart disease (heart disease caused by narrowing or blockage of blood vessels supplying the heart muscle) and seizures.

Xtandi is not for use in women and must not be given to women who are or may become pregnant.

### **Why is Xtandi authorised in the EU?**

The European Medicines Agency considered that the anticancer effects of Xtandi have been clearly demonstrated and that its benefit in prolonging life of patients with metastatic disease is important for patients. Xtandi has also been shown to delay the development of metastatic disease. Regarding the medicines' safety profile, the side effects with Xtandi are generally mild and can be managed appropriately.

The Agency therefore concluded that Xtandi'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 Xtandi?**

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

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

### **Other information about Xtandi**

Xtandi received a marketing authorisation valid throughout the EU on 21 June 2013.

Further information on Xtandi can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/Xtandi](https://ema.europa.eu/medicines/human/EPAR/Xtandi).

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