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EPAR summary for the public

Xtandi

enzalutamide

This is a summary of the European public assessment report (EPAR) for Xtandi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Xtandi.

For practical information about using Xtandi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Xtandi and what is it used for?

Xtandi is a cancer medicine used to treat men with prostate cancer that has spread to other parts of the body and is castration resistant (i.e. worsens despite treatment to lower production of testosterone or after surgical removal of the testes).

Xtandi is used in the following situations:

- when treatment with docetaxel (a cancer medicine) has not worked or no longer works;
- when 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).

The medicine contains the active substance enzalutamide.

How is Xtandi used?

Xtandi is available as capsules (40 mg) and tablets (40 and 80 mg) and can only be obtained with a prescription. The usual dose is 160 mg once a day, at about the same time each day. The doctor may have to reduce the dose or interrupt treatment if a patient gets certain side effects.

For further information, see the package leaflet.

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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?

Xtandi has been compared with placebo (a dummy treatment) in a main study involving 1,199 patients with 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 18.4 months, compared with 13.6 months for patients given placebo.

Xtandi has also been compared with placebo in a second main study involving 1,717 patients with 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. The average survival of patients treated with Xtandi was around 32.4 months compared with 30.2 months for patients treated with placebo. In addition patients treated with Xtandi lived for longer without their disease showing signs of worsening in a radiographic scan: 19.7 months compared with 5.4 months for patients treated with placebo.

What are the risks associated with Xtandi?

The most common side effects with Xtandi (which may affect more than 1 in 10 people) are tiredness, headache, hot flushes and hypertension (high blood pressure). Other important side effects include falls, fractures, cognitive disorder (problems with thinking, learning and memory), and neutropenia (low levels of neutrophils, a type of white blood cells). In addition, seizures (fits) can occur in around 5 patients in 1,000. For the full list of all side effects reported with Xtandi, see the package leaflet.

Xtandi is not for use in women and must not be given to women who are or who may be pregnant. For the full list of restrictions, see the package leaflet.

Why is Xtandi approved?

The European Medicines Agency considered that the anticancer effects of Xtandi had been clearly demonstrated and that its benefit in prolonging life is important for patients. Regarding its safety, the side effects with Xtandi were generally mild and could be managed appropriately.

The Agency therefore concluded that Xtandi's benefits are greater than its risks and recommended that it be approved 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.

Other information about Xtandi

The European Commission granted a marketing authorisation valid throughout the European Union for Xtandi on 21 June 2013.

The full EPAR for Xtandi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Xtandi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2017.