LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Enzalutamide SUN (enzalutamide)

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Summary Public Assessment Report

Enzalutamide SUN
enzalutamide

Film-coated tablet, 40 mg, 80 mg, 160 mg

This is a summary of the public assessment report (PAR) for Enzalutamide SUN. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Enzalutamide SUN and what is it used for?

40 mg, 80 mg: The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Xtandi.

160 mg: The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as a different strength. The reference medicine for the product is Xtandi.

The product is used in the treatment of prostate cancer in adult men:

- That no longer responds to a hormone therapy or surgical treatment to lower testosterone

Or

- That has spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone

Or

- Who had prior prostate removal or radiation and have rapidly rising PSA, but cancer has not spread to other parts of the body and responds to a hormone therapy to lower testosterone

How does Enzalutamide SUN work?

The product works by blocking the activity of hormones called androgens (such as testosterone). By blocking androgens, enzalutamide stops prostate cancer cells from growing and dividing.

How is Enzalutamide SUN used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Enzalutamide SUN have been shown in studies?

Because the 160 mg product is a hybrid application of Xtandi, clinical studies have been provided to show efficacy for the difference of Enzalutamide SUN from the reference product Xtandi. For the 40 mg and 80 mg products, no additional studies were needed as the product is a generic medicine considered to be bioequivalent to the reference medicine, Xtandi. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Enzalutamide SUN?
For a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Enzalutamide SUN approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Xtandi, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Enzalutamide SUN?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Enzalutamide SUN
The full PAR for Enzalutamide SUN can be found on the following website: MRI - Home. For more information about treatment with Enzalutamide SUN, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-04.