



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Orserdu (*elacestrant*)

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

What is Orserdu and what is it used for?

Orserdu is a cancer medicine used to treat postmenopausal women and men with breast cancer that is locally advanced or metastatic (has spread to other parts of the body).

Orserdu can only be used when the cancer cells have receptors (targets) for the hormone oestrogen on their surface (oestrogen receptor-positive; ER-positive) and do not have large quantities of a receptor for human epidermal growth factor called HER2 (HER2-negative). The cancer cells must also have been shown to have a specific mutation (change) in the gene called *ESR1*. Orserdu is used in patients whose cancer has not responded to or has progressed further following at least one hormone treatment, including a medicine belonging to the class of CDK 4/6 inhibitors.

Orserdu contains the active substance elacestrant.

How is Orserdu used?

Orserdu can only be obtained with a prescription and treatment should be started by a doctor experienced in the use of cancer medicines.

Orserdu is available as tablets to be taken by mouth once a day. Treatment should continue for as long as the patient benefits from it or side effects become unmanageable.

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

How does Orserdu work?

ER-positive breast cancer is stimulated to grow when the hormone oestrogen attaches to receptors on cancer cells. The active substance in Orserdu, elacestrant, blocks and destroys these receptors; as a result, oestrogen no longer stimulates these cancer cells to grow and this slows down the growth of the cancer.

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What benefits of Orserdu have been shown in studies?

Orserdu was investigated in one main study involving 478 patients with ER-positive, HER2-negative breast cancer that had started to spread, and whose cancer had come back or did not respond to at least one previous treatment. The study showed that, among patients whose cancer cells had an *ESR1* mutation, those treated with Orserdu lived on average for 3.8 months without their disease getting worse, compared with 1.9 months for patients who received standard therapy.

What are the risks associated with Orserdu?

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

The most common side effects with Orserdu (which may affect more than 1 in 10 people) include nausea (feeling sick), decreased appetite, increased levels of fats and cholesterol in the blood, vomiting, tiredness, dyspepsia (indigestion), diarrhoea, back pain, joint pain, constipation, headache, hot flush, abdominal (belly) pain, anaemia (low levels of red blood cells), increased blood levels of alanine and aspartate aminotransferase (a sign of liver problems) or creatinine (a sign of kidney problems), and decreased blood levels of calcium, sodium and potassium.

Why is Orserdu authorised in the EU?

Orserdu was shown to be effective at increasing the time before the disease got worse in patients with ER-positive and HER2-negative breast cancer that is advanced or has spread and who have an *ESR1* mutation. Orserdu's safety is in line with other medicines of the same class and its side effects are considered manageable. The European Medicines Agency therefore decided that Orserdu'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 Orserdu?

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

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

Other information about Orserdu

Orserdu received a marketing authorisation valid throughout the EU on 15 September 2023.

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

ema.europa.eu/medicines/human/EPAR/orserdu.

This overview was last updated in 09-2023.