swissmedic

Public Summary SwissPAR dated 24 September 2024

Orserdu® (active substance: elacestrant)

Authorisation in Switzerland: 4 June 2024

Film-coated tablets as second-line treatment for monotherapy of post-menopausal women with ER-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation.

About the medicinal product

Orserdu contains the active substance elacestrant. It is used to treat women who have already gone through the menopause (post-menopausal women) and who have a specific type of breast cancer that is already locally advanced or has spread to other parts of the body (metastasised). Orserdu is intended for the treatment of estrogen receptor (ER)-positive breast cancer, i.e. the cancer cells have receptors for the hormone estrogen. The breast cancer must also be negative for human epidermal growth factor receptor 2 (HER2-negative), i.e. the cancer cells have no or only very few such receptors on their surface. Orserdu is used as monotherapy (i.e. as the only medication) in female patients whose breast cancer has not responded to at least one previous hormone treatment combined with a CDK-4/-6 inhibitor or that progressed after such treatment and whose breast cancer has changes (mutations) to the ESR1 gene.

Effect

ER-positive breast cancer cells are stimulated to grow when the hormone estrogen binds to the respective receptor. Elacestrant, the active substance in Orserdu, blocks and destroys these receptors. This means that the hormone estrogen is no longer able to bind to the tumour cells to stimulate growth. The spread of the breast cancer is reduced.

Use

Orserdu is available only on prescription as film-coated tablets.

The recommended dose is 1 film-coated tablet containing 345 mg once a day.

Orserdu should be taken at approximately the same time every day with food. The film-coated tablet must be swallowed whole and should not be crushed or split before swallowing.

Efficacy

The efficacy of Orserdu was investigated in the pivotal trial EMERALD (RAD1901-308).
This trial included 478 female patients with ER-positive, HER2-negative advanced or metastatic breast cancer who showed a progression of disease symptoms following 1–2 previous hormone treatments and up to 1 previous chemotherapy regimen.
The patients were treated with either Orserdu 345 mg daily or the standard therapy (fulvestrant or aromatase inhibitors).
The primary endpoint was progression-free survival (PFS)[1] in all patients and in patients with ESR1 mutations.

In patients with ESR1 mutations, the median[2] PFS was 3.8 months with treatment with Orserdu compared with 1.9 months with the standard therapy.
The proportion of patients whose breast cancer did not advance for 1 year (PFS rate) was 26.8% in the Orserdu group compared with 8.2% in the standard therapy group.
The median overall survival (OS)[3] in patients with ESR1 mutation was 24.2 months with Orserdu therapy compared with 23.5 months with standard therapy.

Precautions, undesirable effects, & risks

Orserdu must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects (affecting more than 1 in 10 users) are decreased appetite, nausea, increased levels of triglycerides and cholesterol in the blood, vomiting, tiredness, indigestion, diarrhoea, decreased blood levels of calcium, back pain, high concentrations of creatinine in the blood, joint pain, low blood levels of sodium, constipation, headache, hot flush, abdominal pain, low levels of haemoglobin in the blood, and increased levels of liver enzymes in the blood.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Female patients with an ESR1 mutation previously had only limited treatment options, particularly after the failure of existing therapies.

Orserdu shows an extension of progression-free survival (PFS) compared with the current standard treatments, with a clinically relevant increase in the proportion of patients who had no disease progression for 1 year (PFS rate after 12 months).

The benefit for progression-free survival combined with an acceptable safety profile, which – other than an increased rate of gastrointestinal complaints – largely corresponds to that of the standard treatments, justifies the authorisation.

[1] Progression-free survival (PFS): period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[2] Median: the value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

[3] Overall survival (OS): refers to the period between the start of treatment and the death of the patient.

Swissmedic has therefore authorised the medicinal product Orserdu, containing the active substance elacestrant, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Orserdu®

Information for patients (package leaflet): Information for patients Orserdu®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.