

# Optimising endocrine-based therapy after CDK4/6 inhibitors in ER+/HER2- advanced breast cancer: emerging biomarkers and their role

**Friday 14th June 2024, 08:00–08:45 BST**

**Clarence Room, DoubleTree by Hilton Metropole, Brighton, UK**

Join our expert faculty to learn about emerging biomarkers and their use in treatment-decision making, and the latest clinical data on KORSERDU ▼ (elacestrant) to optimise outcomes for patients with ER+/HER2- advanced or metastatic breast cancer.



**Dr Mukesh Mukesh**

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**Prof. Samreen Ahmed**

Consultant Oncologist,  
University Hospital  
Leicester NHS Trust

Time (BST)	Session title	Speaker
08:00–08:05	Welcome and introductions	Dr Mukesh
08:05–08:15	Considerations in ER+/HER2- metastatic breast cancer and the role of genomic mutations in guiding treatment choice	Dr Mukesh
08:15–08:25	KORSERDU (elacestrant) and the EMERALD trial	Dr Mukesh
08:25–08:40	<i>ESR1</i> mutation testing and liquid biopsy: Lessons from lung cancer	Prof. Ahmed
08:40–08:45	Q&A discussion and close	All

# KORSERDU ▼ (elacestrant) Great Britain Prescribing Information.

**Qualitative and quantitative composition:** Each film-coated tablet contains elacestrant dihydrochloride equivalent to 345 mg elacestrant, or 86 mg elacestrant. For the full list of excipients, see section 6.1 of the SmPC.

**Therapeutic indications:** KORSERDU monotherapy is indicated for the treatment of postmenopausal women, and men, with estrogen receptor (ER) positive, HER2-negative, locally advanced or metastatic breast cancer with an activating *ESR1* mutation who have disease progression following at least one line of endocrine therapy including a CDK 4/6 inhibitor.

**Posology and method of administration:** Treatment should only be initiated and monitored by a physician experienced in the use of anticancer therapies.

**Posology:** The recommended dose is 345 mg (one 345 mg film-coated tablet), once daily. The maximum recommended daily dose of KORSERDU is 345 mg. Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs. Dose should be modified in response to adverse events or patient tolerability. See SmPC 4.2 for full information on dose modifications.

**Special populations:**

- Elderly (≥ 65 years):** No dose adjustment is required on the basis of patient age.
- Renal impairment:** No dose adjustment is required for patients with mild or moderate renal impairment. Elacestrant has not been studied in patients with severe renal impairment therefore no dose recommendation can be made.
- Hepatic impairment:** No dose adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A). In patients with moderate hepatic impairment (Child-Pugh B), the dose of KORSERDU should be reduced to 258 mg. Elacestrant has not been studied in patients with severe hepatic impairment (Child-Pugh C), therefore no dose recommendation can be made.
- Paediatric population:** The safety and efficacy of KORSERDU in children below the age of 18 years of age has not been established.

**Method of administration:** KORSERDU is for oral use. Tablets should be swallowed whole. They should not be chewed, crushed or split prior to swallowing. Patients should take their dose of KORSERDU at approximately the same time each day. KORSERDU should be administered with a light meal. Administration with food may also reduce nausea and vomiting (see section 5.2 of SmPC for further detail).

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC.

**Special warnings and precautions for use:** for full information and recommendations on management, please see SmPC

section 4.4.

**Concomitant use with strong and moderate CYP3A4 inhibitors:** Concomitant administration of KORSERDU with strong and moderate CYP3A4 inhibitors should be avoided. An alternative concomitant medicinal product with no or minimal potential to inhibit CYP3A4 should be considered. If the strong/moderate CYP3A4 inhibitor cannot be avoided, KORSERDU dose adjustment should be applied (see sections 4.2 and 4.5 of SmPC).

**Concomitant use with CYP3A4 inducers:** Concomitant administration of KORSERDU with strong CYP3A4 inducers should be avoided. An alternative concomitant medicinal product with no or minimal potential to induce CYP3A4 should be considered. If the strong CYP3A4 inducer cannot be avoided, KORSERDU dose adjustment should be applied (see sections 4.2 and 4.5 of SmPC).

**Undesirable effects (summary only, see SmPC for full details):**

**The following undesirable effects are very common (≥1/10):** Anaemia, decreased appetite, headache, hot flush, nausea, vomiting, diarrhoea, constipation, abdominal pain, dyspepsia, arthralgia, back pain, fatigue, raised ALT/AST, raised triglycerides, raised cholesterol, raised creatinine, decreased calcium, decreased sodium, decreased potassium.

**The following undesirable effects are common (≥1/100, <1/10):** UTI, decreased lymphocytes, insomnia, dizziness, syncope, dyspnoea, cough, stomatitis, rash, pain in extremities, musculoskeletal chest pain, bone pain, asthenia, increased blood alkaline phosphatase.

**The following undesirable effects are considered serious:** nausea, dyspnoea, thromboembolism (venous).

**Legal classification:** POM (Prescription Only Medicine).

**Marketing authorisation holder:** Stemline Therapeutics B.V., Basisweg 10, 1043 AP Amsterdam, Netherlands.

**Marketing authorisation number:** PLGB 53425/0003: 86mg; PLGB 53425/0004: 345mg.

**Cost (excluding VAT):** 28 x 86 mg tablets, £2467; 28 x 345 mg tablets, £7340.

**Date of text:** December 2023 (MAT-UK-ELA-00036)

## Adverse Event Reporting

Adverse events should be reported.

Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Stemline Therapeutics Medical Information on 0800 047 8675.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

**CDK4/6**, cyclin-dependent kinase 4 or 6; **ER**, oestrogen receptor; **ESR1**, oestrogen receptor 1;

**HER2**, human epidermal growth factor receptor 2; **NHS**, National Health Service;

**Q&A**, question and answer; **UKOF**, UK Oncology Forum.