

ELACESTRANT (Korserdu)

INDICATION (ICD10) C50

Check the most recent *Blueteq* eligibility criteria before prescribing. *Blueteq* registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (ELAC1)

1. Elacestrant monotherapy for oestrogen receptor-positive, with an activating ESR1 mutation HER2-negative, locally advanced or metastatic breast cancer, which is not amenable to curative treatment, in patients previously treated with at least 12 calendar months of therapy with a CDK4/6 inhibitor-based and endocrine combination but has had no more than 1 prior line of cytotoxic chemotherapy for advanced/metastatic disease. Is an appropriate candidate for the use of further endocrine therapy. PS 0 or 1.

REGIMEN

ELACESTRANT 345mg tablet oral once daily continuously

CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 28 days until disease progression or unacceptable toxicity

ADMINISTRATION

Elacestrant is available as 86mg and 345mg tablets.

Swallow whole, if taken with food may reduce gastrointestinal effects.

Grapefruit and grapefruit juice should be avoided while on elacestrant.

If a dose is missed, it can be taken immediately within 6 hours after the time it is usually taken.

After more than 6 hours, the dose should be skipped for that day.

ANTI-EMETICS

Low risk all days

CONCURRENT MEDICATION REQUIRED

Elacestrant	Loperamide for diarrhoea
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EXTRAVASATION AND TYPE OF LINE / FILTERS

Not applicable

INVESTIGATIONS

Blood results required before SACT administration

FBC, U&Es & LFTs every cycle

Neutrophils $\geq 1.0 \times 10^9/l$ platelets $\geq 100 \times 10^9/l$ and Hb $\geq 9g/dl$ before initiation.

Estimated GFR $\geq 30ml/min/1.73m^2$ or calculated CrCl $\geq 30ml/min$

ALT $\leq 3 \times ULN$, AST $\leq 3 \times ULN$, total bilirubin $\leq ULN$ total bilirubin

Baseline weight

MAIN TOXICITIES AND ADVERSE REACTIONS

Elacestrant	Anaemia Diarrhoea Nausea Acute hepatic failure Rash
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INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
(not exhaustive list check SPC/BNF/Stockleys)

Elacestrant	Strong CYP3A4 inhibitors (eg clarithromycin, itraconazole, posaconazole, voriconazole) should be avoided. CYP3A4 inducers (eg carbamazepine, phenytoin) should be avoided. Grapefruit and grapefruit juice should be avoided
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DOSE MODIFICATIONS

Elacestrant dose

Recommended dose 345mg once daily

First dose adjustment 258mg once daily

Second dose adjustment Discontinue

Non-haematological

Elacestrant

Grade 2	Consider interruption of elacestrant until recovery to grade ≤ 1 or baseline. Then resume elacestrant at the same dose level.
Grade 3	Elacestrant should be interrupted until recovery to grade ≤ 1 or baseline. The dose should be reduced to 258mg once daily when resuming therapy. If the grade 3 toxicity recurs, elacestrant should be interrupted until recovery to grade ≤ 1 or baseline. The reduced dose of 258mg may be resumed if at the discretion of the treating physician the patient is benefiting from treatment. If a grade 3 or intolerable adverse reaction recurs, elacestrant should be permanently discontinued.
Grade 4	Interrupt elacestrant until recovery to grade ≤ 1 or baseline. The dose should be reduced to 258mg once daily when resuming therapy. If a grade 4 or intolerable adverse reaction recurs, permanently discontinue elacestrant.

Hepatic impairment

Elacestrant

No dose adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A). In patients with moderate hepatic impairment (Child-Pugh B), elacestrant dose should be reduced to 258mg.

Elacestrant has not been studied in patients with severe hepatic impairment (Child-Pugh C), therefore no dose recommendation can be made for patients with severe hepatic impairment

Renal impairment

Elacestrant

No dose adjustment in subjects with renal impairment is necessary. Elacestrant has not been studied in patients with severe renal impairment, therefore no dose recommendation can be made for patients with severe renal impairment.

REFERENCES

1. CDF list www.england.nhs.uk/publication/national-cancer-drugs-fund-list/