21 May 2026
EMA/114517/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Etcamah

camizestrant

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Etcamah, intended for the treatment of ER-positive, HER2-negative locally advanced or metastatic breast cancer in patients with *ESR1* gene mutations.

The applicant for this medicinal product is AstraZeneca AB.

Etcamah will be available as 75 mg film-coated tablets. The active substance of Etcamah is camizestrant, an anti-oestrogen endocrine therapy (ATC code: L02BA05). Camizestrant is an oral selective oestrogen receptor degrader (ngSERD) and complete oestrogen receptor (ER) antagonist. It blocks the activity of ERα encoded by both wild-type and mutated *ESR1* and induces proteasome-dependent degradation of ERα, without agonising ERα.

The benefit of Etcamah in combination with a CDK4/6 inhibitor in adults with ER-positive, HER2-negative locally advanced or metastatic breast cancer is an improved progression-free survival (PFS) when patients are switched to camizestrant following detection of an *ESR1* mutation while on first-line treatment with a combination of an aromatase inhibitor (AI) and a CDK4/6 inhibitor, compared with continuing the same AI and a CDK4/6 inhibitor combination.

The most common side effects with Etcamah in combination with a CDK4/6 inhibitor include neutropenia, visual effects, infections, anaemia, diarrhoea, nausea, fatigue, bradycardia and leukopenia.

The full indication is:

> Etcamah in combination with a CDK4/6 inhibitor (palbociclib, ribociclib, or abemaciclib) is indicated for the treatment of adult patients with ER-positive, HER2-negative, locally advanced or metastatic breast cancer upon detection of *ESR1*-mutation and without disease progression during first-line endocrine therapy in combination with a CDK4/6 inhibitor (for biomarker based patient-selection, see section 4.2 and 5.1).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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In pre- or peri-menopausal women and in men, Etcamah plus a CDK4/6 inhibitor should be combined with a luteinizing hormone releasing hormone (LHRH) agonist or antagonist.

Treatment with Etcamah should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.