# US FDA approves AstraZeneca's new breast cancer pill Etcamah: Dosage, high risk and side effects — All you need to know

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The US Food and Drug Administration (FDA) said on Friday it granted accelerated approval to AstraZeneca Plc's breast cancer pill, expanding treatment options for adult patients with advanced breast cancer.

The drug, known as camizestrant, can be used in combination with other cancer medicines in patients who have a genetically driven form of metastatic breast cancer.

AstraZeneca said camizestrant, which will go by the brand name ETCAMAH®.

Etcamah is a cancer medicine used to treat adults with breast cancer that is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body); it is used in combination with a medicine belonging to the class of CDK4/6 inhibitors (palbociclib, ribociclib, or abemaciclib).

ETCAMAH is also approved in more than 30 countries across the globe, including in the EU, Japan, Canada, the UK and several other countries based on the SERENA-6 Phase III trial.

**Doses and risks**

Etcamah works as a hormone therapy by stopping estrogen from stimulating cancer cells, which helps prevent those cells' growth. The drugmaker has shown the pill can help delay disease progression by more than six months.

The drug's patients are those with breast cancer who have a specific mutation that can develop during treatment with an endocrine therapy. Patients will need to have an FDA-authorised test showing they have this mutation before receiving Etcamah.

"Approval [was] based on SERENA-6 Phase III trial results which showed combination reduced the risk of disease progression or death by 56% in patients with an emergent ESR1 tumor mutation," AstraZeneca said.

**Dosage:** ETCAMAH is a potent, next-generation oral selective estrogen receptor degrader (SERD) and complete ER antagonist, administered orally, once daily.

The recommended dose of ETCAMAH in combination with a CDK4/6 inhibitor is 75 mg, AstraZeneca said.

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

“Etcamah 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 until they develop unacceptable side effects,” says the European Medicines Agency.

**High risk:** The drug poses a high risk to pregnant women. "Based on findings in animals and the mechanism of action, ETCAMAH can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus," the company said.

It also advised women not to breastfeed during treatment with ETCAMAH and for one week after the last dose.

**Side effects:** According to the European Medicines Agency , the most common side effects with Etcamah in combination with a CDK4/6 inhibitor (which may affect more than 1 in 10 people) include neutropenia (low level of neutrophils, a type of white blood cell), visual effects (including photopsia, the perception of flashes of light in the field of vision), infections, diarrhoea, nausea (feeling sick), anaemia (low levels of red blood cells), tiredness, bradycardia (slow heart rate) and leucopenia (low levels of white blood cells).

Among these, side effects specifically associated with Etcamah were visual effects and bradycardia. Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include infections and fever.

**What else do we know about breast cancer pill Etcamah**

The approval was based on results from the pivotal SERENA-6 Phase III trial presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in The New England Journal of Medicine.

Earlier this year, the FDA’s Oncology Drugs Advisory Committee voted against the medicine, finding it didn’t have a “meaningful benefit” for patients. In Friday’s approval, however, the agency said the medicine will give women with breast cancer an additional way to treat the disease.

Kevin Kalinsky, MD, MS, FASCO, Division Director of Medical Oncology, Winship Cancer Institute of Emory University and investigator for the trial, said: “The combination provides an important new option for the one in three patients with this form of advanced breast cancer whose tumors develop ESR1 mutations before clinical or radiographic disease progression."

"Today’s approval will enable clinicians to promptly intervene and change therapeutic strategy at an earlier opportunity ahead of disease progression, rather than waiting until the cancer becomes harder to treat, and patient outcomes and quality of life worsen," Kalinsky said.

Breast cancer is the most common cancer in women in the US, with more than 300,000 new patients diagnosed annually, and more than 42,000 deaths, the FDA reported citing WHO data.

Under Chief Executive Officer Pascal Soriot, AstraZeneca has launched a raft of blockbuster cancer drugs. The company is looking to secure continued growth from its pipeline of oncology drugs while also positioning itself to compete in the red-hot market for weight-loss treatments.

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