Package leaflet: Information for the patient

Etcamah® 75 mg film-coated tablets
camizestrant

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Etcamah is and what it is used for

What Etcamah is

Etcamah contains the active substance camizestrant. Camizestrant belongs to a group of medicines called oral selective oestrogen receptor degrader (SERD) and oestrogen receptor (ER) antagonists.

What Etcamah is used for

Etcamah is a cancer medicine used in adults in combination with another cancer medicine known as a CDK4/6 inhibitor (palbociclib, ribociclib or abemaciclib) to treat breast cancer that has spread nearby (locally advanced) or that has spread to other parts of the body (metastatic). It is important that you also read the package leaflet for these other medicines. If you have any questions about these medicines, ask your doctor.

Etcamah can only be used when the cancer cells have receptors (targets) on their surface called as oestrogen receptor-positive (ER-positive) and do not have large quantities of a receptor for human epidermal growth factor called HER2 (HER2-negative). The cancer cells must also have been shown to have a change (mutation) in a gene called '*ESR1*' which has been detected while the patient was receiving anti-hormonal therapy together with a CDK4/6 inhibitor as the first treatment for the cancer, while the cancer is not getting worse. Your doctor will also perform a test to make sure that Etcamah is right for you.

When Etcamah is used in women who have not yet reached the menopause (pre-menopausal or perimenopausal) and men, it should be given with a luteinising hormone-releasing hormone (LHRH) agonist or antagonist (medicines that lower blood levels of hormones, such as oestrogen, progesterone and testosterone).

How Etcamah works

The active substance in Etcamah, camizestrant, works by directly blocking and destroying oestrogen receptors found in breast cancer. Oestrogen receptors are proteins that can help the breast cancer grow and multiply. By blocking and destroying the oestrogen receptors found in breast cancer, Etcamah can reduce the growth and spread of the cancer.

2. What you need to know before you take Etcamah

Do not take Etcamah
- if you are breast-feeding.
- if you are allergic to camizestrant or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Etcamah
- if you have reduced heart rate**.**
- if you have any liver-related problems.

Children and adolescents
Do not give this medicine to children or adolescents aged less than 18 years. This is because it is not known how well Etcamah works, or how safe it is in this age group.

Other medicines and Etcamah
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Etcamah can affect the way some other medicines work. Also, some other medicines can affect the way Etcamah works.

- The following medicines can reduce the effectiveness of Etcamah by reducing the amount of Etcamah in the blood:
  - Carbamazepine (used for seizures)
  - St John's Wort (a herbal medicine used for depression)
  - Rifampicin (used to treat certain infections)
- Phenobarbital (used for seizures) and other known moderate CYP3A4/5 inducers may reduce the effectiveness of Etcamah, and they should be used with caution. If possible, your doctor may consider alternative medicines.
- Etcamah can increase the risk of side effects with of some other medicines by increasing the amount of these medicines in the blood. These include:
  - Omeprazole, pantoprazole (used to treat conditions caused by excess stomach acid)
  - Warfarin (used to treat blood clots)
  - Phenytoin (used to treat seizures)

  If you are taking any of these medicines, your doctor will stop the treatment at least 2 weeks before your first dose of Etcamah and will not restart it until at least 2 weeks after your last dose of Etcamah.
- Lansoprazole (used to treat conditions caused by excess stomach acid) and other known moderately sensitive substrates of CYP2C9 and/or CYP2C19 - may be used with caution. If possible, your doctor may consider alternative medicines.
- Medicines known as sensitive CYP3A4/5 substrates for example:
  - Midazolam (used for sleep and/or relieve anxiety) and simvastatin (used to lower cholesterol) - should be used with caution.
  - Alfentanil and fentanyl (medicines used for pain relief) - may require dose adjustments and your doctor may closely monitor their use for possible adverse reactions.
- Taking Etcamah with some medicines may increase the risk of altering your heart rhythm resulting in abnormal electrical activity of the heart (QT prolongation) and Torsades de Pointes (abnormal electrical activity in the heart with life-threatening rhythm disturbance). These include:

- Ciprofloxacin, levofloxacin (used to treat bacterial infection)
- Ondansetron (used to treat nausea and vomiting)
- Escitalopram, venlafaxine (used to treat depression)
- Fluconazole (used to treat fungal infection)
- **Ribociclib** (used for breast cancer in combination with Etcamah)

Ribociclib - Taking Etcamah together with ribociclib has been studied. Your doctor will monitor you during treatment with these medicines and may adjust doses, if necessary. See ribociclib package leaflet for more information.

What you need to know about monitoring with Etcamah and CDK4/6 inhibitors
Before and after you start treatment with Etcamah and a CDK4/6 inhibitor, your doctor will check your heart with an ECG and do blood tests, including checking your blood salts, if required. During treatment, your doctor will continue to monitor you as needed and follow the instructions for the CDK4/6 inhibitor you are taking. If there are changes in your heart rhythm, you may need ECG checks more often.

Pregnancy, breast-feeding and fertility

Birth control (contraception) - information for women and men

Female patients
If you are a woman who can become pregnant, you must use effective birth control while taking Etcamah and for at least 4 weeks after your last dose. Do not use birth control pills. Choose a non-hormonal method like a copper coil. Ask your doctor about suitable methods of contraception.

Male patients
- You must use a condom when having sex with a female partner, even if she is pregnant, while taking Etcamah and for at least 1 week after taking the last dose.
- Your female partner must also use contraception such as the birth control pill.
- You must tell your doctor if your female partner becomes pregnant.

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. This is because Etcamah can harm your unborn baby.
- If you do become pregnant during treatment, tell your doctor straight away. Your doctor will decide with you whether you should carry on taking Etcamah.
- Do not become pregnant while taking this medicine. If you are able to become pregnant, you must use effective contraception. See 'Birth control (contraception) – information for women and men' above.
- If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start treatment to check if you are already pregnant. You may also need to do regular pregnancy tests while you are having Etcamah.

Breast-feeding
Before taking Etcamah, tell your doctor, if you are breast-feeding. It is not known whether the medicine passes into breast milk. For the safety of your baby, you must not breastfeed during treatment with Etcamah and for 4 weeks after taking the last dose.

Fertility
Etcamah may decrease fertility in men and women. Talk to your doctor or pharmacist for advice if you are planning to have a baby.

Driving and using machines
Etcamah is taken together with a CDK4/6 inhibitor, which may cause you to feel tired or dizzy and this can slightly affect your ability to drive or use machines. Etcamah on its own may sometimes cause brief changes in the side of your vision, such as seeing flashes of light. These changes are usually mild

and do not normally affect driving. If this happens, use caution when driving or operating tools or machines.

Etcamah contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Etcamah

Always take this medicine exactly as your doctor has told you - ask your doctor or pharmacist if you are not sure.
- Etcamah is available as film-coated tablets which are taken by mouth.
- The recommended dose of Etcamah is one 75 mg film-coated tablet taken once a day at the same time each day.
- Swallow the tablet whole with water. Do not chew, crush, dissolve or divide the tablet.
- Etcamah can be taken with or without food.
- If you vomit, do not take an extra dose. Take the next dose of Etcamah at your usual time.
- Treatment should continue for as long as you benefit from it or the side effects become unmanageable.

If you take more Etcamah than you should
If you take more Etcamah than you should, contact your doctor. Take the tablets and this leaflet with you.

If you forget to take Etcamah
If you forgot to take a dose, you can take it immediately within 6 hours from the time you usually take it. If it is more than 6 hours from the time you usually take your dose, then skip that dose and take the next dose of Etcamah at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Etcamah
Do not stop taking Etcamah unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor if you get any side effects, including those not listed in this leaflet.

Tell your doctor immediately if you get any of the following symptoms during the treatment:
Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, abdominal pain and diarrhoea, warm or painful areas on your body, or feeling very tired (signs or symptoms of infections) (very common, may affect more than 1 in 10 people).

Other side effects:

Very common: may affect more than 1 in 10 people
- Low levels of neutrophils, a type of white blood cell (neutropenia)
- Low levels of white blood cell (leucopenia)
- Low levels of platelets, a componenent that helps the blood to clot (thrombocytopenia)
- Low level of red blood cells (anaemia)
- Dizziness

- Headache
- Visual effects
- Dry eye
- Slow heart rate (bradycardia)
- Cough
- Diarrhoea
- Feeling sick (nausea)
- Vomiting
- Back pain
- Tiredness (fatigue)
- Weakness (asthenia)

Common: may affect up to 1 in 10 people
- Low levels of lymphocytes, a type of white blood cell (lymphopenia)
- Loss of appetite
- Reduced level of potassium in the blood, which could lead to disturbance in heart rhythm (hypokalaemia)
- Reduced level of phosphate in the blood (hypophosphataemia)
- Reduced level of calcium in the blood, which may sometimes lead to cramps (hypocalcaemia)
- Strange taste in the mouth (dysgeusia)
- Fainting (syncope)
- Blood clot in a deep vein, usually in the leg (deep vein thrombosis)
- Shortness of breath or difficulty breathing (dyspnoea)
- Constipation
- Abdominal (belly) pain
- Mouth sores or ulcers with gum inflammation (stomatitis)
- Itching (pruritus)
- Hair loss (alopecia)
- Increased levels of liver enzymes which can be a sign of liver problems
- High blood levels of creatinine, a breakdown product of muscle, which can be a sign of kidney problems
- Abnormal electrical activity of the heart that affects its rhythm (QTc prolongation)

Uncommon: may affect up to 1 in 100 people
- Low levels of white blood cells with fever due to infection (febrile neutropenia)
- Severe irregular heartbeat (Torsades de Pointes) that can cause dizziness, fainting, or collapse
- Obstruction of a blood vessel by a clot (embolism)
- Clot in a blood vessel in the lungs which can cause chest pain, breathlessness and fainting (pulmonary embolism)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etcamah

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not use Etcamah if you notice the package or container show signs of damage or tampering or if the tablets are broken, cracked, or otherwise not intact.

Ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Etcamah contains

- The active substance is camizestrant. Each film-coated tablet contains 75 mg of camizestrant.
- The other ingredients are:
  Tablet core: Cellulose, microcrystalline (type 102), calcium hydrogen phosphate, sodium starch glycolate (Type A) and magnesium stearate (see section 2 'Etcamah contains sodium').
  Tablet coating: Polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide red (E172), iron oxide yellow (E172), and iron oxide black (E172).

What Etcamah looks like and contents of the pack

Etcamah 75 mg film-coated tablets (tablets) are beige, round, bi-convex, film-coated tablet, debossed with 'CM' above '75' on one side and plain on the reverse. Approximate diameter: 9 mm.

Etcamah is supplied in 28x1 film-coated tablets in aluminium/aluminium perforated unit dose blisters (each pack contains 2 blisters with 14 film-coated tablets).

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AstraZeneca UK Limited,
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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product name	**Marketing Authorisation number**
Etcamah 75 mg film-coated tablets	PL 17901/0390

This is a service provided by the Royal National Institute of the Blind.