

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ETCAMAH™** **camizestrant tablets**

This Patient Medication Information is written for the person who will be taking **ETCAMAH**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ETCAMAH**, talk to a healthcare professional.

What ETCAMAH is used for:

ETCAMAH is used with other cancer drugs to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, breast cancer. The breast cancer:

- is outside the breast or has spread to other parts of the body, and
- has changes in a gene called 'ESR1', and
- is found during estrogen lowering-based therapy.

How ETCAMAH works:

ETCAMAH works by directly blocking and destroying proteins that help breast cancer grow and multiply. This cuts down on the growth and spread of the cancer.

The ingredients in ETCAMAH are:

Medicinal ingredient(s): camizestrant

Non-medicinal ingredients: calcium hydrogen phosphate, iron oxide black, iron oxide red, iron oxide yellow, macrogol 3350, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium starch glycolate (type A), talc, titanium dioxide.

ETCAMAH comes in the following dosage form(s):

Tablets; 75 mg camizestrant

Do not use ETCAMAH if:

You are allergic to camizestrant or to any ingredients in ETCAMAH or the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ETCAMAH. Talk about any health conditions or problems you may have, including if you:

- Have severe liver problems.
- Have eye problems.
- Have heart or heart rhythm problems.

Other warnings you should know about:

Female Patients: pregnancy, breastfeeding, birth control

- Do not become pregnant while taking ETCAMAH. ETCAMAH can harm your unborn baby if you become pregnant.

- If you are pregnant, think you may be pregnant or able to get pregnant, there are risks you should discuss with your healthcare professional.
- If you do become pregnant during treatment, tell your healthcare professional right away. They will decide if you should still take ETCAMAH.
- If you are able to become pregnant:
 - Your healthcare professional will do a pregnancy test before you start taking ETCAMAH. This test must show that you are not pregnant. You will do more pregnancy tests during the course of your treatment.
 - Avoid becoming pregnant while you are taking ETCAMAH. Use effective birth control during your treatment and for 4 weeks after your last dose. The birth control must not contain hormones. Ask your healthcare professional about methods of birth control available to you.
- Do not breastfeed while you are taking ETCAMAH and for at least 1 week after your last dose.

Male Patients: birth control

- During treatment with ETCAMAH, use birth control each time you have sex with a woman who is able to get pregnant. Continue using birth control for 1 week after your last dose. The birth control must not contain hormones.
- Your female partner must also use a suitable method of contraception. You must tell your healthcare professional if your female partner becomes pregnant.

Fertility

- Treatment with ETCAMAH may affect your ability to have or father a child. If you have questions about this, talk to your healthcare professional.

Effects on vision:

- ETCAMAH can cause vision side effects like:
 - brief trailing or floating lights in your vision, blurry vision, dry eyes, increased sensitivity of the eyes to light.
- These vision side effects can happen within a few weeks after starting ETCAMAH treatment. Talk to your healthcare professional right away if you notice new or worsening vision symptoms.

Children and adolescents (under 18 years old)

- Do not give ETCAMAH to children or adolescents aged less than 18 years old.

Driving and using machines

- ETCAMAH can cause vision problems. You should be careful when driving or using machines during treatment with ETCAMAH.

Check-ups and testing:

- You will have regular visits with your healthcare professional, before, during and at the end of your treatment. They will:
 - Check your heart rate and rhythm during treatment. An Electrocardiogram (ECG) assessment should be done.
 - Check your eye health before and during treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ETCAMAH:

- Medicines used to treat seizures such as carbamazepine, phenobarbital, phenytoin.
- An herbal treatment for depression called St. John's Wort.
- Medicines used to treat excess stomach acid such as omeprazole, lansoprazole.
- A medicine used as a blood thinner called warfarin.
- A medicine used to lower cholesterol called simvastatin.
- A medicine used to produce sleepiness or drowsiness called midazolam.
- A medicine used to treat multiple sclerosis called siponimod.
- A medicine used to treat nausea and vomiting called ondansetron.
- A medicine used to treat bacterial infections such as ciprofloxacin.
- A medicine used to treat cancer called ribociclib. Taking ETCAMAH with ribociclib may increase the risk of heart problems.

The medicines listed here may not be the only ones that could interact with ETCAMAH.

How to take ETCAMAH:

- Always take ETCAMAH exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Swallow tablet whole with water. Do not chew, crush, dissolve or divide the tablets.
- Take ETCAMAH with or without food.
- For women who have not reached menopause and for some men, your healthcare professional might tell you to take a medicine that lowers sex hormone levels. Your healthcare professional will tell you how much of this medicine you will take and how to take it.

Usual dose:

Adults: Take one 75 mg tablet once per day by mouth at about the same time each day. You will also receive treatment with another medicine (palbociclib, ribociclib or abemaciclib). Your healthcare professional will tell you how much of this medicine you will take and how to take it.

Overdose:

If you think you, or a person you are caring for, have taken too much ETCAMAH, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

- If you miss a dose, you may take it right away 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.
- Do not take a double dose to make up for a forgotten dose. Take the next dose of ETCAMAH at the usual time.
- If you vomit after taking your dose, do not take another dose. Take the next dose of ETCAMAH at the usual time.

Possible side effects from using ETCAMAH:

These are not all the possible side effects you may have when taking ETCAMAH in combination with other cancer drugs. If you experience any side effects not listed here, tell your healthcare professional.

- tiredness
- feeling unwell
- dry eyes
- cough
- dizziness
- nausea, vomiting
- itchy skin
- joint pain
- hot flushes

ETCAMAH can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how ETCAMAH is affecting your blood and heart.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very Common			
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness.		✓	
Bradycardia (abnormally slow heartbeat).		✓	
Effects on vision: brief trailing or floating lights in your vision, blurry vision, dry eyes, increased sensitivity of the eyes to light.		✓	
Neutropenia, Leukopenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep out of the reach and sight of children.
- Store between 2°C to 30°C in original package.
- Do not use:
 - after the expiry date on the package or container. The expiry date refers to the last day of that month
 - if you notice the package or container has signs of damage or tampering
 - if the tablets are broken, cracked.

Return any unused medication to your healthcare professional. Ask your healthcare professional how to throw away medicines you no longer use. Do not throw away any medicines in wastewater or household waste. These measures will help protect the environment.

If you want more information about ETCAMAH:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website www.astrazeneca.ca; or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

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