

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRUQAP® capivasertib tablets

This Patient Medication Information is written for the person who will be taking **TRUQAP**. 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 **TRUQAP**, talk to a healthcare professional.

Serious warnings and precautions box

TRUQAP may cause:

- Serious skin reactions, including:
 - **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)**, a serious skin reaction that may affect one or more organs;
 - **Erythema Multiforme (EM)**, an allergic skin reaction; and
 - **Palmar-plantar erythrodysesthesia**, a skin reaction that affects palms of hand and soles of your feet.
- **Hyperglycemia** (high blood glucose levels), including **diabetic ketoacidosis** (a complication of diabetes, where your body produces high levels of blood acids). Some cases have been fatal.
- **Severe diarrhea**, which may cause dehydration and acute kidney injury (when your kidneys suddenly stop working properly).

What TRUQAP is used for:

TRUQAP is a prescription medication used in combination with another medicine called fulvestrant. It is used in adult females to treat breast cancer which is advanced or has spread to other parts of the body and has progressed on or after endocrine therapy. The breast cancer must be hormone receptor-positive and HER2-negative, with an abnormal *PIK3CA*, *AKT1*, and/or *PTEN* gene.

Your healthcare professional will test your cancer for abnormal *PIK3CA/AKT1/PTEN* genes to make sure that TRUQAP is right for you.

How TRUQAP works:

TRUQAP works by blocking the effects of proteins called *AKT* kinases. These proteins help cancer cells to grow and multiply. By blocking their action, TRUQAP can reduce growth and spread of the cancer and help to destroy cancer cells. The combination of capivasertib and fulvestrant results in increased anti-tumour activity.

TRUQAP will only be prescribed to you by a healthcare professional with experience in the use of medicines for cancer.

The ingredients in TRUQAP:

Medicinal ingredient: capivasertib

Non-medicinal ingredients: calcium hydrogen phosphate, copovidone, croscarmellose sodium, hypromellose, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), macrogols 3350, magnesium stearate, microcrystalline cellulose, polydextrose, purified water, titanium dioxide, triglycerides (medium-chain).

TRUQAP comes in the following dosage forms:

Tablets: 160 mg and 200 mg

Do not use TRUQAP if:

- you are allergic to capivasertib or to any of the other ingredients of TRUQAP.

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

- have or have ever had diabetes or high levels of sugar in your blood. TRUQAP has not been studied in patients who use insulin to treat diabetes or in patients with high blood sugar levels at the start of treatment.
- have risk factors for hyperglycemia:
 - a family history of diabetes
 - a current infection
 - are taking steroids or other chemotherapy medications
 - are dehydrated or suffer from excessive vomiting, diarrhea or sweating
 - are malnourished
 - are obese
- have diarrhea or loose stools.
- have a history of rash or other skin problems.
- have kidney problems or high levels of creatinine or uric acid in your blood.
- have liver problems.

Other warnings you should know about:

- **TRUQAP may cause serious side effects including:**
 - **Severe diarrhea.** Your healthcare professional will monitor your health. They may give you medicine to manage the diarrhea and recommend that you drink more fluids during treatment with TRUQAP to avoid getting dehydrated.
 - **Severe hyperglycemia** (high blood sugar levels). Talk to your healthcare professional **right away** if you get any signs of increased sugar levels, such as excessive thirst, dry mouth, more frequent urination or a bigger amount of urine than normal, confusion, nausea, vomiting, fruity odour on breath, dry or flushed skin, and increased appetite with weight loss. Your healthcare professional may need to give you medicine to bring your sugar levels back to normal. If you have risk factors for hyperglycemia you should discuss lifestyle changes with your healthcare professional to help you manage your blood sugar levels. Some patients taking TRUQAP developed diabetic ketoacidosis (a serious complication of high blood

sugar) less than 10 days after starting treatment. In some cases diabetic ketoacidosis has been fatal.

- **Pregnancy and birth control**

- If you are pregnant or plan to be pregnant during treatment with TRUQAP, there are important risks you should discuss with your healthcare professional.
- Do NOT become pregnant during treatment with TRUQAP. It could harm your unborn baby.
- If you are able to become pregnant, you should use an effective method of birth control during your treatment and for at least 4 weeks after your last dose of TRUQAP.
- If you become pregnant during treatment with TRUQAP, talk to your healthcare professional right away.

- **Breastfeeding**

- Do NOT breastfeed during treatment with TRUQAP. It is unknown if TRUQAP passes into your breast milk.
- Talk to your healthcare professional about the best way to feed your baby during treatment with TRUQAP.

- **Check-ups and testing**

You will have regular visits with your healthcare professional during your treatment with TRUQAP. They will monitor your blood sugar levels by testing for your:

- Fasting glucose levels (blood sugar levels after not eating for at least 8 hours). This will be done before treatment with TRUQAP, and regularly during treatment.
- Glycosylated hemoglobin levels (a marker of blood sugar level over the last 8 to 12 weeks). This will be done before treatment and approximately every 3 months during treatment.

If you have a history of diabetes or are at greater risk of elevated blood glucose, your blood sugar levels may be monitored more frequently.

- **Children and adolescents (under 18 years of age):** Children under 18 years of age should not be given TRUQAP.
- **Adults 65 years or older:** You may be at a greater risk of serious side effects if you are 65 years of age or older.
- **Driving and using machinery:** TRUQAP can cause fatigue. Before you drive or do tasks that require special attention, wait until you know how you respond to TRUQAP.

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 TRUQAP:

- Some medicines used to treat infections caused by bacteria (clarithromycin, erythromycin, josamycin, nafcillin, rifabutin, rifampin, telithromycin, troleandomycin).
- Medicines used to treat fungal infections (fluconazole, itraconazole, ketoconazole,

- posaconazole, voriconazole).
- Medicines used to treat viral infections (boceprevir, cobicistat, efavirenz, ensitrelvir, etravirine, indinavir, lersivirine, lopinavir, nevirapine, ritonavir, saquinavir, talviraline, telaprevir).
- Medicines used to prevent seizures or to treat epilepsy (carbamazepine, cenobamate, phenobarbital, phenytoin).
- An herbal medicine used for depression (St. John's wort).
- Certain medicines used to treat heart conditions or high blood pressure (bosentan, dofetilide, mibefradil, procainamide).
- A medicine used to treat a sleep disorder called narcolepsy (modafinil).
- A medicine used to treat cancer pain (fentanyl).
- Medicines used to reduce the body's immune response (cyclosporine, tacrolimus).
- Medicines used to treat mental health problems (pimozide, thioridazine).
- Medicines used to lower blood cholesterol levels (statins e.g. simvastatin).
- A medicine used to treat low blood sodium levels (conivaptan).
- A medicine used to treat a rare disorder called Hutchinson-Gilford progeria syndrome (lonafarnib).
- A medicine used to medically end early pregnancy (mifepristone).
- A medicine used to treat pain associated with a condition called endometriosis (elagolix).
- A medicine used to treat high uric acid in the blood that might cause a condition known as gout (lesinurad).
- A medicine used in the treatment of Alzheimer's Disease (semagacestat).
- A medicine used to treat diarrhea associated with a condition called carcinoid syndrome (telotristat ethyl).
- Some medicines used to treat cancer (dabrafenib, idelalisib, lorlatinib, pexidartinib, ribociclib, sotorasib, tucatinib, ceritinib).

How to take TRUQAP:

- Take TRUQAP exactly as your healthcare professional tells you.
- Take TRUQAP 2 times each day (about 12 hours apart), at about the same times each day with or without food.
- Do NOT take any tablets that are broken, cracked, or that look damaged.
- Swallow TRUQAP tablets whole with water. Do NOT chew, crush, or split the tablets.
- Grapefruit may interact with TRUQAP. You should not drink or eat grapefruit products during treatment with TRUQAP.
- Your healthcare professional will prescribe TRUQAP in combination with another medicine called fulvestrant. Your healthcare professional will tell you how to take it.
- For women who have not reached menopause:
 - Your healthcare professional will also prescribe a medicine called a luteinizing hormone-releasing hormone (LHRH) agonist during your treatment with TRUQAP.

Usual dose:

Recommended dose of TRUQAP (in combination with fulvestrant):

Adults: 400 mg (two 200 mg TRUQAP tablets) twice daily for 4 days, followed by 3 days off treatment. This is a total daily dose of 800 mg. Refer to the dosing schedule below.

TRUQAP dosing schedule for each week

	Day 1	Day 2	Day 3	Day 4	Day 5*	Day 6*	Day 7*
Morning	2 x 200 mg	2 x 200 mg	2 x 200 mg	2 x 200 mg			
Evening	2 x 200 mg	2 x 200 mg	2 x 200 mg	2 x 200 mg			

* No dosing on Day 5, 6 and 7

- If you have side effects, your healthcare professional may need to change your dose, temporarily stop or completely stop treatment with TRUQAP.
- Do NOT change your dose or stop taking TRUQAP unless your healthcare professional tells you.

Overdose:

If you think you, or a person you are caring for, have taken too much TRUQAP, 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 of TRUQAP, you may still take it within 4 hours from the time you usually take it.
- If it has been more than 4 hours after you usually take your dose, skip the missed dose. Take the next dose at your usual time. Do NOT take 2 doses to make up for a missed dose. Refer to table above for dosing schedule.
- If you vomit after taking a dose of TRUQAP, do NOT take a replacement dose. Take your next dose at your usual time.

Possible side effects from using TRUQAP:

These are not all the possible side effects you may have when taking TRUQAP. If you experience any side effects not listed here, tell your healthcare professional.

- Diarrhea
- Dry mouth
- Nausea
- Vomiting
- Mouth sores or ulcers with gum inflammation
- Rash, skin reddening, blistering of lips, eyes or mouth, skin peeling, skin inflammation, dry skin, itching
- Tiredness
- Headache
- Fever
- Weight loss
- Strange taste in the mouth
- Upset stomach, indigestion
- Pain, redness and swelling of mucosa in different parts of the body e.g., of genital mucosa

Your healthcare professional will order some tests before and during treatment. These include blood tests to monitor your blood sugar level. More frequent blood tests may be needed. Your

health professional will tell you if your blood test results are abnormal and if you need treatment to correct these side effects.

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			
Diarrhea: increased number of bowel movements. Watery stool. Stomach pain and/or cramps		✓	
Other gastrointestinal problems: nausea, vomiting, stomach pain, decreased appetite, heartburn, bloating or indigestion	✓		
Hyperglycemia (high blood sugar): increased thirst, frequent urination, larger amounts of urine, increased appetite with weight loss, dry mouth, confusion, nausea, vomiting, fruity odour on breath, dry or flushed skin		✓	
Skin reactions: skin redness with flaking/peeling or rash		✓	
Stomatitis (mouth sores, redness and swelling of the lining of the mouth) or inflammation of other mucosa: ulcer or sore, red and inflamed areas on the lips or inside the mouth or nose; inflamed lining of the eye or vagina		✓	
Common			
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): pain or burning when urinating, bloody or cloudy urine, foul smelling urine		✓	
Hypokalemia (low levels of potassium in blood): muscle weakness and spasms, irregular heartbeats	✓		

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Dermatitis exfoliative generalised (a skin reaction where large areas of skin are flaking or peeling): shedding and/or scaling of skin surface			✓
Acute kidney injury (loss of kidney function): not passing urine, swelling of the legs or around the eyes, feeling tired, shortness of breath, confusion, nausea			✓
Rash called erythema multiforme: raised red or purple skin patches, possibly with blister or crust in the center; possibly swollen lips, mild itching or burning			✓
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect one or more organs): fever, severe rash, swollen lymph glands, flu-like feeling, swelling of the face; possibly yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinate less often, less urine			✓
Palmar-plantar erythrodysesthesia syndrome (also called Hand-Foot Syndrome): reddening and/or swelling, peeling on the palms and soles, tingling sensation and burning pain of the feet		✓	
Diabetic ketoacidosis (a serious complication of high blood sugar): nausea, vomiting, abdominal pain, difficulty breathing, fruity odour on breath, confusion, unusual fatigue or sleepiness		✓	

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:

Store at room temperature between 15°C to 30°C in original package.

Keep out of reach and sight of children.

If you want more information about TRUQAP:

- 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: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; 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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