



A Guide to Your Treatment with TRUQAP[®]



This brochure can help you understand your treatment.

Now that you have been prescribed TRUQAP, you might have some questions.

Read this carefully before you start treatment with TRUQAP. This leaflet is a summary and will not tell you everything about this drug.

Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about TRUQAP.

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Get to know TRUQAP

What is TRUQAP?

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 (HR+) and HER2-negative (HER2-), with an abnormal *PIK3CA*, *AKT1*, and/or *PTEN* gene.

Biomarker testing

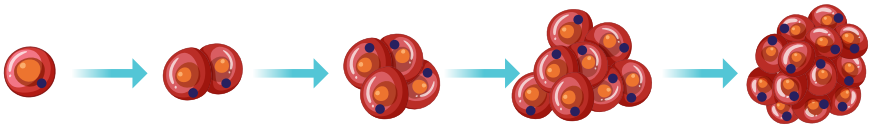
TRUQAP is for people with HR+/HER2- advanced or metastatic breast cancer who test positive for abnormal *PIK3CA*, *AKT1*, and/or *PTEN* genes.

Your healthcare professional will test your cancer for these abnormal genes to make sure that TRUQAP is right for you.

The abnormal genes can also be referred to as biomarkers, mutations or alterations.

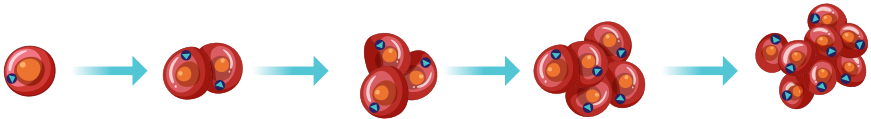
How does TRUQAP work?

Proteins called AKT kinases help cancer cells to grow and multiply.



TRUQAP works by blocking AKT kinases.

By blocking their action, TRUQAP can reduce growth and spread of the cancer and help to destroy cancer cells.



Legend

● AKT kinase

▶ TRUQAP

TRUQAP + fulvestrant

The combination of TRUQAP and fulvestrant results in increased anti-tumour activity.

Precautions when it comes to TRUQAP

Serious warnings and precautions with TRUQAP treatment

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).

Do not use TRUQAP if:

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

TRUQAP contains the following:

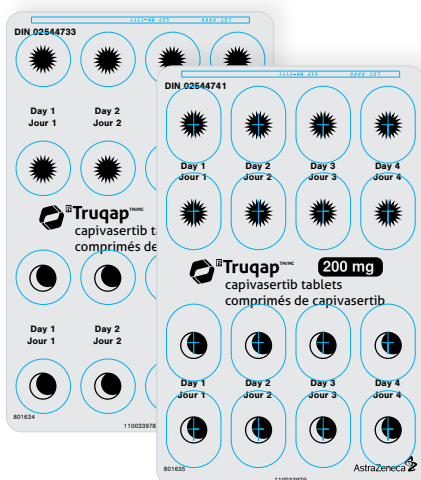
- ▶ **Medicinal ingredients:** capivasertib;
- ▶ **Non-medicinal ingredients:** calcium hydrogen phosphate, copovidone, croscarmellose sodium, hypromellose, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), macrogols 3350, magnesium stearate, microcrystalline cellulose, polydextrose,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



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:
 - 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.

Dosing and administration



Morning Dose

Take 2 x 200 mg tablets



Evening Dose

Take 2 x 200 mg tablets

Usual dose

Recommended dose of TRUQAP (in combination with fulvestrant):

Adults: 400 mg (2 x 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.

Your healthcare professional will prescribe TRUQAP in combination with an injectable medicine called fulvestrant. Your healthcare professional will tell you how it's administered.

TRUQAP dosing schedule for each week

TRUQAP							+	fulvestrant
Day	1	2	3	4	5	6		7
AM	 200 mg x2	 200 mg x2	 200 mg x2	 200 mg x2	No Dose			
PM	 200 mg x2	 200 mg x2	 200 mg x2	 200 mg x2	No Dose			

Usual dose of fulvestrant

500 mg
(2 injections)
administered on
Days 1 and 15 of the
first 28-day cycle
and then on Day 1
of each following
28-day cycle

- ▶ 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 to.



Discuss with your healthcare professional when to start your treatment with TRUQAP.

Dosing and administration

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.



Take TRUQAP with or without food.



Swallow TRUQAP tablets whole with water. Do not chew, crush, or split the tablets.



Do not take any tablets that are broken, cracked, or that look damaged.



Grapefruit may interact with TRUQAP. You should not drink or eat grapefruit products while on treatment with TRUQAP.



Your healthcare professional will prescribe TRUQAP in combination with an injectable medicine called fulvestrant. Your healthcare professional will tell you how it's administered.

Usual dose of fulvestrant used with TRUQAP is 500 mg (2 injections) administered on Days 1 and 15 of the first 28-day cycle, and then on Day 1 of each following 28-day cycle.



If you 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.

Missed dose



If you miss a dose of TRUQAP:

- You can take it within 4 hours from the time you usually take it.

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 the above dosing schedule.



Don't double up

- If you vomit after taking a dose of TRUQAP, do not take a replacement dose. Take your next dose at your usual time.

Overdose

If you think you, or a person you are caring for, have taken too much TRUQAP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Side effects when it comes to TRUQAP

What are 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, contact your healthcare professional.



- Diarrhea



- Nausea



- Vomiting



- Upset stomach, indigestion (dyspepsia)



- Rash, skin reddening, blistering of lips, eyes or mouth, skin peeling, skin inflammation, dry skin, itching (pruritus)



- Pain, redness and swelling of mucosa in different parts of the body, e.g., of genital mucosa (mucosal inflammation)



- Dry mouth



- Mouth sores or ulcers with gum inflammation (stomatitis)



- Strange taste in the mouth (dysgeusia)



- Tiredness



- Headache



- Fever



- Weight loss

Potential serious side effects from using TRUQAP and what to do about them



Talk to your healthcare professional if you experience any of these symptoms or side effects.

Very common



Diarrhea: increased number of bowel movements, watery stool, stomach pain and/or cramps



Other gastrointestinal disorders (if serious): 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

Uncommon



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 experience any of the symptoms or side effects listed below, stop taking TRUQAP and get immediate medical help.

- ▶ **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

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

Managing select side effects

You may experience side effects at any time while taking TRUQAP + fulvestrant.

It's important to talk with your healthcare professional about side effects. They may have tips and advice.

Here is some information regarding selected side effects you may experience.

Selected common side effects	Supportive measures	Management tips
 Diarrhea	- Follow a low-fibre diet (e.g., bananas, rice, applesauce, dry toast, crackers, eggs, fish, and poultry) - Avoid triggers such as caffeine and alcohol, high-fibre foods, dairy products and spicy or acidic foods	- Contact your healthcare professional immediately and take any prescribed medication as directed - Your healthcare team may recommend taking medicine to help stop or slow your diarrhea - Drink enough fluids daily to stay hydrated: - Fluids include non-carbonated, caffeine-free, clear fluid such as water, oral rehydration solutions or broth - Modify diet and eating patterns (e.g., eating smaller meals, more often)

Selected common side effects	Supportive measures	Management tips
 Nausea	▪ Eat small amounts throughout the day instead of 3 large meals ▪ Avoid strong smells ▪ Ask someone else to prepare and cook your food	▪ Contact your healthcare professional immediately if nausea is severe ▪ Follow the directed treatment plan by your healthcare professional ▪ Drink cool or room-temperature beverages ▪ Eat foods that have helped alleviate nausea in the past
 Skin reactions	▪ If your healthcare provider has prescribed any emollients, keep them on hand ▪ Use mild soaps ▪ Bathe with cool or lukewarm water ▪ Avoid lotions and creams that have alcohol, perfume or dye ▪ Avoid being out in the sun - If you go outside, use a broad-spectrum sunscreen that has zinc oxide or titanium dioxide	▪ Contact your healthcare professional to report skin changes such as rash, redness, itchiness, dryness, flaking or peeling on face, body, hands and feet ▪ These may be recommended by your healthcare team: emollients, topical corticosteroids, systemic steroids or non-sedating oral antihistamines. Ask your healthcare team to learn more

Managing select side effects

Selected common side effects	Supportive measures	Management tips
 High blood sugar	▪ Eat at regular times, and don't skip meals ▪ Choose foods lower in calories, saturated fat, sugar, and salt ▪ Track your food, drink, and physical activity ▪ Drink water instead of juice or soda ▪ Limit alcoholic drinks ▪ Control your food portions ▪ Complete all tests requested by your healthcare team in a timely manner - if your blood test results are abnormal, you may need treatment to correct these side effects - Ensure that you follow fasting requirements for accurate results	▪ Contact your healthcare professional immediately if you experience any symptoms of high blood sugar such as: - Increased thirst - Increased urination (frequency or volume) - Increased appetite - Weight loss - Fatigue - Dry mouth - Confusion - Nausea/vomiting - Fruity odour on the breath - Dry or flushed skin

Selected common side effects	Supportive measures	Management tips
 Tiredness	▪ Adopt healthy sleep habits ▪ Eat healthy - Speak to a dietitian about your diet ▪ Schedule time to relax ▪ Limit stress ▪ Cut back on caffeine ▪ Keep track of your fatigue and plan activities around your energy levels by noting the times of day when you have the most energy or what may contribute to your fatigue	▪ Ask for help with errands and chores ▪ Try to stay active with gentle exercises such as walking, yoga, and tai chi
 Stomatitis (Symptoms can include mouth sores [ulcers], redness and swelling of the lining of the mouth, pain, bleeding, and trouble eating and drinking)	▪ Check your mouth, gums and tongue every day for signs of mouth sores and inform your healthcare team immediately of any changes ▪ Follow your oral healthcare plan as recommended: - Rinse your toothbrush in hot water to help soften it before brushing - Use a very soft toothbrush - Clean your teeth and mouth within 30 minutes after eating - Rinse your toothbrush in hot water after using and keep it in a clean, dry place	▪ Contact your healthcare professional immediately ▪ Follow updated oral care plan from your healthcare team ▪ Maintain good nutrition

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.



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.



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.



Children and adolescents (under the age of 18)

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.

Track your side effects

Use the tracker sheets in your TRUQAP Tracker to record any side effects that occur while you are taking TRUQAP.

Note: days when you take your treatment are shaded blue.

																
Examples	Diarrhea	Nausea	Vomiting	Upset stomach, indigestion	Rash, skin redness, itching or flaking of lips, eyes or mouth, skin peeling, skin inflammation, dry skin, itching	Pain, redness and swelling of tissues in different parts of the body	Strange taste in the mouth	Mouth sores or ulcers with open inflammation (aphthous)	Dry mouth	Tiredness	Headache	Fever	Notes (including other potential side effects)			
WEEK 1	DAY 1 (treatment)	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 2	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 3	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 4	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 5	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
WEEK 2	DAY 6	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 7	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 8	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 9	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 10	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
WEEK 3	DAY 11	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 12	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 13	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 14	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 15	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
WEEK 4	DAY 16	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 17	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 18	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 19	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 20	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
WEEK 5	DAY 21	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 22	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 23	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 24	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 25	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 26	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 27	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				
	DAY 28	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot				

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



Contact your healthcare professional if you notice any change to your overall health during your treatment with TRUQAP.

Reporting side effects

You can report suspected side effects to Health Canada by:



- ▶ Visiting the Web page on Adverse Reaction 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.



- ▶ You can also report suspected side effects to your healthcare professional or by scanning this QR code.



Helpful links

To access these resources, please scan the QR codes below.



Canadian Breast Cancer Network



Rethink Breast Cancer



Canadian Cancer Society



Quebec Breast Cancer Foundation

Questions?

The AstraZeneca Oncology Patient Support Program (PSP) is here for you to answer any questions you may have about TRUQAP and our support services.



1-877-280-6208

Monday to Friday 8:00 am to 8:00 pm, ET
(including Federal holidays)

On weekends, statutory holidays and Ontario public holidays, the PSP line will take voicemail, and calls will be returned the next business day.



enrollment@azoncologypsp.ca

If you want more information about TRUQAP:



- ▶ Talk to your healthcare professional



- ▶ Scan to access the TRUQAP Patient Medication Information



- ▶ Scan to access resources and support materials by visiting **TRUQAP.ca**

Note: You will need your TRUQAP DIN to access the website.