

TRUQAP®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using TRUQAP?

TRUQAP contains the active ingredient capivasertib. TRUQAP is used in combination with another medicine called fulvestrant to treat adults who have hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer that is advanced or that has spread to other parts of the body and whose cancer is not responding to other anti-hormonal based therapies.

For more information, see Section [1. Why am I using TRUQAP?](#) in the full CMI.

2. What should I know before I use TRUQAP?

Do not use if you have ever had an allergic reaction to capivasertib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding

For more information, see Section [2. What should I know before I use TRUQAP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRUQAP and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TRUQAP?

- The usual dose of TRUQAP is two 200 mg tablets taken twice daily for 4 days followed by 3 days off treatment. However your doctor may prescribe a different dose if you are taking certain medicines or if you experience certain side effects.
- Continue using TRUQAP for as long as your doctor tells you to.

More instructions can be found in Section [4. How do I use TRUQAP?](#) in the full CMI.

5. What should I know while using TRUQAP?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using capivasertib.● Ensure you are using effective contraception (man or woman). Even if you stop treatment, you should continue to use effective contraception for at least a further 4 weeks if you are a woman and a further 16 weeks if you are a man.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine or change the dose unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">● TRUQAP may affect your ability to drive or use machines. If you feel tired while taking TRUQAP, take special

	care when driving or using tools or machines.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your tablets in a cool, dry place where the temperature stays below 30°C. • Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using TRUQAP?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include nausea, vomiting, tiredness, mouth sores or ulcers. However, some serious side effects may need medical attention. These can include diarrhoea, high blood sugar levels, severe blistering, peeling or scaling of skin or skin reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TRUQAP

Active ingredient: *capivasertib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRUQAP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TRUQAP.**

Where to find information in this leaflet:

- [1. Why am I using TRUQAP?](#)
- [2. What should I know before I use TRUQAP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TRUQAP?](#)
- [5. What should I know while using TRUQAP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TRUQAP?

TRUQAP contains the active ingredient capivasertib. Capivasertib belongs to a group of medicines called AKT inhibitors. 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.

TRUQAP is used to in combination with another medicine called fulvestrant to treat adults who have hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer that is advanced or that has spread to other parts of the body and whose cancer is not responding to other anti-hormonal based therapies.

2. What should I know before I use TRUQAP?

Warnings

Do not use TRUQAP if:

- you are allergic to capivasertib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin or
- you may feel faint

Check with your doctor if you:

- You have or have ever had high levels of sugar in your blood or diabetes (or signs of increased sugar levels, such as excessive thirst and dry mouth, needing to pass urine more often than usual, producing greater amounts of urine than usual, increased appetite with weight loss).
- You have diarrhoea or loose stool.
- You have rash or other skin disorders.
- You have kidney problems or high levels of creatinine or uric acid in your blood.
- You have liver problems.
- have any other medical conditions
- take any medicines for any other condition
- you have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or if you (male or female) are planning to have a baby.

If you are pregnant or plan to become pregnant, you should not take TRUQAP. Before taking TRUQAP, tell your doctor if you are pregnant, think you may be pregnant or planning to have a baby as TRUQAP may harm your unborn baby.

If you are a woman who could become pregnant, your doctor will ask you to provide a negative pregnancy test prior to starting treatment and may advise you to perform a pregnancy test during your treatment. If you are able to become pregnant, you should use effective birth control during treatment with TRUQAP and for 4 weeks after the last dose.

Male patients should use condoms and effective birth control during treatment and for 16 weeks after the last dose.

If you or your partner do become pregnant during the treatment tell your doctor right away.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

For the safety of your baby, you should not breast-feed during the treatment with TRUQAP.

Children and Adolescents

The safety and efficacy of TRUQAP has not been established in children or adolescents. Do not give this medicine to children or adolescents aged less than 18 years.

Monitoring before and during treatment with TRUQAP

It is important that you have your blood sugar monitored during treatment. Your doctor will perform blood tests to measure your blood sugar levels before you start taking TRUQAP and during treatment. Based on the results, your doctor may decide to temporarily interrupt treatment with TRUQAP or reduce the dose of TRUQAP or decide to stop the treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or have recently been taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some products may interfere with TRUQAP and affect how it works.

Taking TRUQAP with certain other medicines may affect how TRUQAP works and can cause side effects. Some medicines can affect the levels of TRUQAP in your body. Also, TRUQAP can affect the way some other medicines

work. Some medicines may increase the risk of side effects of TRUQAP.

These include:

- antibiotics for treating bacterial infections such as clarithromycin, rifampicin
- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- medicines for epilepsy such as carbamazepine and phenytoin
- St John's Wort, a herbal medicine used to treat depression
- anti-viral medicines such as saquinavir, ritonavir and lopinavir
- bosentan, a medicine used to treat high blood pressure in the lungs
- simvastatin a medicine used to treat high levels of cholesterol
- medicines used to suppress the immune system such as ciclosporin and tacrolimus
- medicines used to treat cancer such as ceritinib, tucatinib.

Avoid drinking large amounts of grapefruit juice while taking TRUQAP as it may increase side effects of TRUQAP.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are or have been taking and if these affect TRUQAP.

4. How do I use TRUQAP?

How much to take

The usual dose of TRUQAP is 400 mg (two 200 mg tablets) taken orally twice daily approximately 12 hours apart (total daily dose of 800 mg) for 4 days followed by 3 days off treatment. Your doctor may prescribe a different dose if you are taking certain medicines that may interact with TRUQAP or if you experience certain side effects while you are taking TRUQAP.

Swallow TRUQAP tablets whole with water. Do not chew, crush, dissolve or divide the tablets. TRUQAP tablets may be taken with or without food.

If you vomit, do not take an additional dose. The next dose of TRUQAP should be taken at your usual time.

Follow the instructions provided and use TRUQAP until your doctor tells you to stop.

TRUQAP is used in combination with another medicine called fulvestrant which is given as an injection. The recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29, and once monthly thereafter.

During your treatment with TRUQAP, for women who have not reached menopause, your doctor will prescribe a medicine called a luteinising hormone releasing hormone (LHRH) agonist.

When to take TRUQAP

TRUQAP should be used at about the same time in the morning and evening of the dosing days.

If you forget to use TRUQAP

If you miss your dose at the usual time, 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 that dose. Take the next dose at your usual time.

Do not take a double dose to make up for the dose you missed.

If you use too much TRUQAP

If you think that you have used too much TRUQAP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TRUQAP?

Things you should do

Call your doctor straight away if you experience the following during treatment with TRUQAP:

- Signs of increased blood sugar levels (hyperglycaemia) and its complications; increased thirst and dry mouth, passing urine more often than usual, increased appetite with weight loss. It is important that you have your blood sugar monitored during treatment. High blood sugar levels may cause a serious condition called diabetic ketoacidosis, which may become life-threatening if it is not treated at an early stage. Symptoms of diabetic ketoacidosis may include feeling sick or being sick, shortness of breath, severe thirst, feeling weak and tired, confusion, a sweet smell to your breath, a sweet or metallic taste in your mouth, a strange odour to your urine or sweat and frequent urination.
- Signs of diarrhoea which may include loose or watery stool. Severe diarrhoea may cause dehydration with symptoms such as dry sticky mouth, severe thirst, dizziness, fatigue, dark-coloured urine or urinating less often than normal or not at all.

- Rash, reddening of the skin, blistering of the lips, eyes or mouth, skin peeling, dry skin, skin inflammation with rash, shedding and/or scaling of skin surface.

Your doctor may need to treat these symptoms, temporarily interrupt your treatment, reduce your dose, or permanently stop your treatment with TRUQAP.

Remind any doctor, dentist or pharmacist you visit that you are using TRUQAP.

Ensure you are using effective contraception. Even if you stop treatment, you should continue to use effective contraception for at least a further 4 weeks if you are a woman and a further 16 weeks if you are a man.

If you become pregnant while you are taking this medicine or within 4 weeks of stopping this medicine, tell your doctor immediately.

If you are a man and your partner becomes pregnant while you are taking this medicine or within 16 weeks of stopping this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. For example, periodic tests will be done to check your blood sugar levels during treatment.

Things you should not do

- Do not stop using this medicine or change the dose unless without checking with your doctor.

- Do not use TRUQAP to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRUQAP affects you.

TRUQAP may affect your ability to drive or use machines. If you feel tired while taking TRUQAP, take special care when driving or using tools or machines.

Looking after your medicine

Keep your tablets below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store your tablets in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Loss of appetite• Strange taste in mouth• Mouth sores or ulcers with gum inflammation• Feeling or being sick (nausea or vomiting)• Upset stomach, indigestion• Tiredness• Itching	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Dry skin ● Rash ● Pain, redness and swelling of mucosa in different parts of the body ● Decrease in the number of red blood cells (anaemia) which can be associated with shortness of breath, fatigue, pale skin, or fast heart beat 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● High blood sugar level (hyperglycaemia). Signs of increased blood sugar levels include nausea, vomiting blurred vision, confusion, increased thirst, dry mouth, passing urine more often than usual. ● Diarrhoea 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Urinary tract infection. Signs of a urinary tract infection can include burning or pain when you pass urine, more frequent or urgent need to urinate, fever, chills, or blood in the urine. ● Rash, skin reddening, blistering of lips, eyes or mouth, skin peeling ● Shedding and/or scaling of skin surface ● Skin inflammation with rash ● Allergic reaction. Signs of an allergic reaction can include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin. 	

Some other serious side effects may only become known through tests. Your doctor will test your blood regularly while you are being treated with TRUQAP.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TRUQAP contains

Active ingredient (main ingredient)	capivasertib
Other ingredients (inactive ingredients)	microcrystalline cellulose calcium hydrogen phosphate croscarmellose sodium

	magnesium stearate hypromellose titanium dioxide macrogol 3350 polydextrose copovidone medium chain triglycerides iron oxide black iron oxide red iron oxide yellow
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Do not take this medicine if you are allergic to any of these ingredients.

What TRUQAP looks like

TRUQAP 160 mg tablets are round, biconvex, beige film-coated tablets debossed with 'CAV' above '160' on one side and plain on the reverse. (Aust R 407961)

TRUQAP 200 mg tablets are capsule-shaped, biconvex, beige film-coated tablets debossed with 'CAV 200' on one side and plain on the reverse. (Aust R 407960).

Who distributes TRUQAP

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone:- 1800 805 342

This leaflet was prepared in May 2024.

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