

# TRUQAP<sup>®</sup> Film-Coated Tablets

Capivasertib 160 mg & 200 mg

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## What TRUQAP is used for

TRUQAP is a medicine used to treat cancer. It contains the active substance capivasertib. Capivasertib belongs to a group of medicines called AKT inhibitors.

TRUQAP is used in combination with fulvestrant (another cancer medicine) to treat adult patients who have oestrogen receptor (ER) positive, HER2 negative breast cancer that is advanced or that has spread to other parts of the body with one or more abnormal “*PIK3CA*”, “*AKT1*”, or “*PTEN*” gene and whose cancer is not responding to other medicines that block the action of hormones (hormone therapy). Women who have not reached menopause will also be treated with a medicine called a luteinising hormone releasing hormone (LHRH) agonist. For men, your doctor will decide if you should be treated with LHRH agonist.

Your healthcare provider will test your cancer to see if it has at least one abnormal “*PIK3CA*”, “*AKT1*”, or “*PTEN*” gene to make sure that TRUQAP is right

for you.

When you take this medicine, you will also be given another medicine called fulvestrant.

## 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 of the cancer cells. If you have any questions about how TRUQAP works or why this medicine has been prescribed for you, ask your doctor.

## Before you use TRUQAP

### - When you must not use it

#### **Do not take TRUQAP if:**

You are allergic to capivasertib or any of the other ingredients of this medicine (listed in section “Product description”).

### *Children and adolescents*

TRUQAP is not recommended for children or adolescents under 18 years of age. The safety of TRUQAP and how effective it is has not been studied in this age group.

### - Before you start to use it

#### **Before you take TRUQAP, tell your healthcare provider if:**

- You have or have ever had diabetes or high blood sugar (hyperglycaemia) or signs of high blood sugar including being very thirsty, having a dry mouth, needing to pass urine more often than usual, passing more urine than usual, having an increased appetite with weight loss.

- You have any current infections.
- You have diarrhoea or loose stools.
- You have a rash or other skin disorders.
- You have kidney problems or high levels of creatinine or uric acid in your blood (seen in blood tests).
- You have liver problems.

Ask your doctor to provide you with the package leaflet for fulvestrant as this contains important information about the medicine.

### - Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines used to treat infection may increase the risk of side effects of TRUQAP and your doctor may need to reduce the dose of TRUQAP. See examples below:

- Certain antibiotics (e.g. clarithromycin, telithromycin).
- Certain antifungals (e.g. ketoconazole, itraconazole, voriconazole, posaconazole).
- Certain antivirals (e.g. boceprevir, nelfinavir, ritonavir, telaprevir).

Some medicines may reduce the effectiveness of TRUQAP, for example carbamazepine, phenytoin, St. John’s Wort (a herbal medicine), and rifampicin.

TRUQAP may also increase the risk of side effects or alter the efficacy with certain other

medicines such as bupropion, carbamazepine, cyclosporine, fentanyl, irinotecan, simvastatin. The doctor may need to adjust the dose of these medicines.

The medicines listed here may not be the only ones that could interact with TRUQAP. Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

**How to use TRUQAP**

- How much to use & when to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The usual starting dose is 400 mg (two 200 mg tablets) taken twice a day (a total of 4 tablets each day) for four days followed by three days of no dose. See Table 1.
- Swallow the tablets whole with water and take them 12 hours apart (2 in the morning and 2 in the evening) at about the same time of day on the dosing days.
- Do not chew, crush or split them before swallowing. Do not swallow any tablet that is broken, cracked or otherwise damaged as you may not be taking the full dose.
- You can take the tablets with or without food.

**Table 1 TRUQAP dosing schedule**

Day	1	2	3	4	5	6	7
☀	#	#	#	#			
☾	#	#	#	#			

\* No dosing on day 5, 6 and 7.  
☀: Morning

☾ : Evening  
# : 2 x 200 mg

Record the day you take your first dose on the carton. While you take TRUQAP, you will also receive another medicine called fulvestrant. Your doctor will determine the dose and the schedule for fulvestrant.

If you vomit, do not take an additional dose. Take the next dose of TRUQAP at your usual time. Avoid grapefruit and grapefruit juice while you are taking TRUQAP as it may increase the side effects of TRUQAP.

Depending on how your body responds to the treatment with TRUQAP, your doctor may adjust your TRUQAP dose. It is very important to follow your doctor’s instructions. If you have certain side effects, your doctor may lower your dose, pause your treatment for a time, or stop your treatment.

The number of tablets to take depends on the dose prescribed as below:

- 400 mg dose: two 200 mg tablets twice daily
- 320 mg dose: two 160 mg tablets twice daily
- 200 mg dose: one 200 mg tablet twice daily

- How long to use it

Take TRUQAP for as long as your doctor tells you to.

This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is working as expected. If you have questions about how long to take TRUQAP, talk to your doctor or to your pharmacist.

- If you forget to use it

If you miss a dose, you can 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. Refer to table 1 for dosing schedule. Do not take two doses to make up for a missed dose.

- If you use too much (overdose)

If you take too many tablets, or if someone else takes your medicine, contact a doctor or hospital for advice immediately. Show the TRUQAP packet and this leaflet. Medical treatment may be necessary.

**While you are using it**

- Things you must do

During your treatment with TRUQAP talk to your doctor immediately if you experience the following side effects. Your doctor may need to treat these symptoms, temporarily pause your treatment, reduce your dose, or permanently stop your treatment with TRUQAP:

High blood sugar levels (hyperglycaemia)

- Your doctor will monitor your blood sugar levels before you start the treatment with TRUQAP but also regularly during treatment with TRUQAP and more frequently in the first eight weeks of the treatment. Your blood sugar levels should be monitored on days 3 or 4 of the dosing week, before you take TRUQAP. Based on the results, your doctor will take any necessary actions, such as prescribing a medicine to lower blood sugar levels and seeking advice from a diabetologist. Your blood sugar levels and

medication will need to be monitored more frequently if you have diabetes.

- Your doctor will tell you exactly when and where to have the blood tests. Treatment with TRUQAP may only be started if tests show that you have the right levels of sugar in your blood. This is because TRUQAP can increase sugar in your blood (hyperglycaemia) which could be serious and cause complications with fatal outcome.
- Signs of high blood sugar include being very thirsty, having dry mouth, needing to pass urine more often than usual, passing more urine than usual, having an increased appetite with weight loss. Additional symptoms such as nausea, vomiting, abdominal pain, difficulty breathing, fruity odour on breath, confusion, unusual fatigue, or sleepiness may be signs of an acute complication of increased blood sugar.

#### Any signs of diarrhoea

- Your doctor or pharmacist will advise you to drink more fluids or take medicines to treat diarrhoea.
- Signs of diarrhoea are loose or watery stools.

#### Rash and other skin drug reactions

- Signs of a rash and other skin drug reactions include 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.

#### - Things you must not do

Do not stop taking TRUQAP unless your doctor tells you to. If you have any further questions on the use of this

medicine, ask your doctor or pharmacist.

#### - Things to be careful of

##### *Pregnancy and fertility*

Do not take TRUQAP if you are pregnant or plan to become pregnant. 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 before starting treatment and advise you to perform a pregnancy test during your treatment.

##### *Contraception for men and women*

If you are a woman, you should avoid becoming pregnant while taking TRUQAP. Discuss contraception with your doctor if there is any possibility that you may become pregnant. 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. If you do become pregnant during treatment, tell your doctor right away. Your doctor can advise you on suitable methods of contraception.

If you are a man, you must use a condom when having sexual intercourse with a female partner who is pregnant or able to become pregnant while you are taking TRUQAP and for 16 weeks after the last dose. Your female partner must also use a suitable method of contraception. You must tell your doctor if your female partner becomes pregnant.

##### *Breast-feeding*

Before taking TRUQAP, tell your doctor if you are breast-feeding. For the safety of your baby, you should not breast-feed during the treatment with TRUQAP.

##### *Driving and using machines*

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.

#### **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. Your doctor may need to treat these symptoms, temporarily pause your treatment, reduce your dose, or permanently stop your treatment with TRUQAP.

#### **High blood sugar levels (hyperglycaemia)**

- 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

Your doctor or pharmacist will monitor your blood sugar levels before you start and during treatment with TRUQAP. They will monitor your blood sugar levels more frequently if you have diabetes.

#### **Diarrhoea**

- Loose or watery stool
- Your doctor or pharmacist will advise you to drink more fluids or take medicine to treat diarrhoea.

#### **Rash and other skin drug reactions**

- 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

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

**Very common (may affect more than 1 in 10 people)**

- Infection of the parts of the body that collect and pass out urine (urinary tract infection)
- Low level of haemoglobin in blood
- Loss of appetite
- Feeling sick (nausea)
- Vomiting
- Mouth sores or ulcers with gum inflammation (stomatitis)
- Itching (pruritus)
- Tiredness
- Headache

**Common (may affect up to 1 in 10 people)**

- Strange taste in the mouth (dysgeusia)
- Upset stomach, indigestion (dyspepsia)
- Skin eruptions
- Pain, redness and swelling of mucosa in different parts of the body, e.g. of genital mucosa (mucosal inflammation)
- High blood level of creatinine seen in blood tests, which may be a sign of kidney problems.
- High blood level of glycosylated haemoglobin (a marker of blood sugar level over the last 8 to 12 weeks)
- Reduced level of potassium in the blood

- Dizziness
- Syncope (fainting)
- Stomach pain
- Fever
- Kidney problems including rapid loss of kidney function (acute kidney injury)
- Weight loss

**Uncommon (may affect up to 1 in 100 people)**

- Hypersensitivity
- Toxic skin eruptions (allergic rash)
- Diabetic ketoacidosis (a serious complication of high blood sugar level)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

**Storage and Disposal of TRUQAP**

**- Storage**

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

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

This medicine should be stored below 30°C.

Do not use this medicine if you notice any damage to the packaging or if the tablet is broken, cracked, or otherwise not intact.

**- Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your

pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

**- What it looks like**

*TRUQAP 160 mg film-coated tablets*

Round, biconvex, beige film-coated tablets debossed with 'CAV' above '160' on one side and plain on the reverse. Approximate diameter: 10 mm.

*TRUQAP 200 mg film-coated tablets*

Capsule shaped, biconvex, beige film-coated tablets debossed with 'CAV 200' on one side and plain on the reverse. Approximate size: 14.5 mm (length), 7.25 mm (width).

TRUQAP is supplied in aluminium blisters (with symbols of sun for the morning/moon for the evening) containing 16 film-coated tablets. Each pack contains 64 tablets (4 blisters).

**- Ingredients**

**Active ingredients:**

The active substance of TRUQAP is capivasertib.

- Each 160 mg TRUQAP film-coated tablet contains 160 mg capivasertib.
- Each 200 mg TRUQAP film-coated tablet contains 200 mg capivasertib.

**Inactive ingredients:**

The other excipients are:

- Tablet core: microcrystalline cellulose (E460i), calcium hydrogen phosphate, croscarmellose sodium (E468) and magnesium stearate (E470b) (see section "Inactive ingredients").
- Film-coating: hypromellose, titanium dioxide (E171), macrogol 3350,

polydextrose, copovidone,  
medium chain triglycerides,  
black iron oxide (E172), red  
iron oxide (E172), yellow  
iron oxide (E172).

This medicine contains less than  
1 mmol sodium (23 mg) per  
dose, that is to say essentially  
'sodium free'.

- MAL number

160mg: MAL25056001ARZ

200mg: MAL25056002ARZ

**Manufacturer**

AstraZeneca AB  
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**Product Registration Holder**

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