

## Package leaflet: Information for the patient

**Truqap<sup>®</sup> 160 mg film-coated tablets**  
**Truqap<sup>®</sup> 200 mg film-coated tablets**  
capivasertib

▼ 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. See the end of section 4 for how to report side effects.

### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Truqap is and what it is used for
2. What you need to know before you take Truqap
3. How to take Truqap
4. Possible side effects
5. How to store Truqap
6. Contents of the pack and other information

#### **1. What Truqap is and what it is used for**

##### **What Truqap is**

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 available in 160 mg and 200 mg tablets.

##### **What Truqap is used for**

Truqap in combination with fulvestrant is used to treat adult patients 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 with one or more abnormal “PIK3CA”, “AKT1”, or “PTEN” gene and whose cancer is not responding to other anti-hormonal based therapies.

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.

##### **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.

If you have any questions about how Truqap works or why this medicine has been prescribed for you, ask your doctor.

## 2. What you need to know before you take Truqap

Follow your doctor's instructions carefully, as they may differ from the general information in this leaflet. Check with your doctor if you are not sure.

### Do not take Truqap if:

You are allergic to capivasertib or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice.

### Warnings and precautions

#### Before you take Truqap, tell your healthcare provider if:

- You have or have ever had high blood sugar or diabetes (or signs of high blood sugar, such as being very thirsty and having dry mouth, needing to pass urine more often than usual, making 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.
- You are taking or have recently taken any other medicine, including medicines obtained without a prescription.
- You are pregnant or plan to become pregnant. Truqap may harm your unborn baby. If you are able to become pregnant, you should use an effective method of birth control during your treatment and at least for 4 weeks after the last dose of Truqap.
- You are breastfeeding or plan to breastfeed. It is not known if Truqap passes into your breast milk. Do not breastfeed during treatment.
- You are a male with female partners who are or able to become pregnant. Male patients should use condoms and effective birth control during treatment with Truqap and for 16 weeks after the last dose. If your female partner becomes pregnant, tell your healthcare provider right away.
- You have poor dental health or history of osteonecrosis of the jaw.

You should read the Package Leaflet of fulvestrant for important information on warnings and precautions.

#### Immediately talk to your doctor if you experience the following during treatment with Truqap:

- High blood sugar levels (hyperglycaemia)
  - Your doctor or pharmacist or nurse 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.
  - For signs of high blood sugar – see Section 4 Possible side effects.
- Any signs of diarrhoea
  - Your doctor or pharmacist or nurse will advise you to drink more fluids or take medicines to treat diarrhoea.
  - For signs of diarrhoea – see Section 4 Possible side effects.
- Any skin reactions
  - For signs of skin reactions – see Section 4 Possible side effects.
- Problems with your mouth, teeth or jaw
  - New or worsening oral symptoms including dental health, pain or swelling and non-healing of mouth sores or discharge.

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

## **Children and adolescents**

Do not give this medicine to children or adolescents under 18 years of age.

## **Other medicines and Truqap**

Tell your doctor or pharmacist or nurse if you are taking, have recently taken or might take any other medicines. Some medicines may increase the risk of side effects 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).
- Drugs to slow or reduce the risk of bone fracture (e.g., alendronate, denosumab)

Some medicines may reduce the effectiveness of Truqap, for example carbamazepine, phenytoin, St. John's wort (an herbal medicine), and rifampicin.

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

## **Pregnancy and fertility**

Do not take Truqap if you are pregnant.

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 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 a woman who could become pregnant, you should use an effective method of birth control during treatment with Truqap and for 4 weeks after the last dose. If you do become pregnant during treatment, tell your doctor immediately.

If you are a man, you must use a condom when having sexual intercourse with a female partner who is or could become pregnant while you are taking Truqap and for 16 weeks after the last dose. Your female partner must also use an effective 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.

## **Truqap contains sodium**

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

### 3. How to take Truqap

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

The usual starting dose of Truqap 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, then repeat. See Table 1
- 12 hours apart at about the same time in morning and evening of the dosing days
- with or without food

**Table 1 Truqap weekly dosing schedule**

Day	1	2	3	4	5*	6*	7*
<b>Morning</b> ☀	2 x 200 mg						
<b>Evening</b> 🌙	2 x 200 mg						

\* No dosing on day 5, 6 and 7

Swallow Truqap tablets whole with water, 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.

If you vomit, do not take an additional dose. Take the next dose of Truqap at your usual time.

Avoid high doses of 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 want to adjust your Truqap dose. It is very important to follow your doctor's instructions. If you have certain side effects, your doctor may ask you to change to a lower dose, to pause treatment for a time, or to stop treatment.

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

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

When you take this medicine, you will also receive another medicine called fulvestrant. Your doctor will determine the dose and the schedule for fulvestrant.

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. For men, your healthcare provider may prescribe a LHRH agonist to take with Truqap and fulvestrant.

#### How long to take Truqap

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 having the desired effect. If you have questions about how long to take Truqap, talk to your doctor or pharmacist or nurse.

#### If you take more Truqap than you should

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. Medical treatment may be necessary.

### **If you forget to take Truqap**

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

### **If you stop taking Truqap**

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 or nurse.

## **4. Possible side effects**

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

### **Some side effects could be serious.**

Immediately talk to your doctor if you experience the following during treatment with Truqap. 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, very common)**

- 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

#### **Skin reactions (very common)**

- Rash
- Reddening of the skin
- Blistering of the lips, eyes or mouth
- Skin peeling
- Skin inflammation with rash
- Shedding and/or scaling of skin surface
- Skin eruptions
- Toxic skin eruptions (allergic rash)

#### **Other side effects**

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

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

- Urinary tract infection
- Low level of red blood cells (anaemia)
- Loss of appetite
- Nausea
- Vomiting
- Diarrhoea
- Mouth sores or ulcers with gum inflammation (stomatitis)
- Itching (pruritus)

- Tiredness

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

- Hypersensitivity
- Strange taste in the mouth (dysgeusia)
- Upset stomach, indigestion (dyspepsia)
- Dry skin
- Pain, redness and swelling of mucosa in different parts of the body, e.g. of genital mucosa (mucosal inflammation)
- High blood level of creatinine
- High blood level of glycosylated haemoglobin (a marker of blood sugar level over the last 8 to 12 weeks)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Truqap**

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 after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Truqap contains**

The active substance of Truqap is capivasertib.

- Each 160 mg Truqap film-coated tablets contains 160 mg capivasertib.
- Each 200 mg Truqap film-coated tablets contains 200 mg capivasertib.

The other excipients are:

- Tablet core: Microcrystalline cellulose, Calcium hydrogen phosphate, Croscarmellose sodium, Magnesium stearate.
- Coating material: Hypromellose, Titanium dioxide (E171), Macrogols, Polydextrose, Copovidone, Medium chain Triglycerides, Black iron oxide (E172), Red iron oxide (E172), Yellow iron oxide (E172).

### **What Truqap looks like and contents of the pack**

#### 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 a pack size of 64 tablets, comprising four Alu/Alu blisters of 16 tablets.

**Marketing Authorisation Holder**

AstraZeneca UK Limited,  
1 Francis Crick Avenue,  
Cambridge,  
CB2 0AA,  
UK.

**Manufacturer**

AstraZeneca AB  
Gärtunavägen  
SE-152 57 Södertälje  
Sweden

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**Other sources of information**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

<b>Product name</b>	<b>Marketing Authorisation number</b>
Truqap 160 mg film-coated tablets	PLGB 17901/0373
Truqap 200 mg film-coated tablets	PLGB 17901/0374

This is a service provided by the Royal National Institute of the Blind.