**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S4

**TRUQAP 160 mg Film-coated Tablets**

**TRUQAP 200 mg Film-coated Tablets**

**(Capivasertib)**

**Contains Sugar - polydextrose**

**Read all of this leaflet carefully before you start taking TRUQAP**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRUQAP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**



## 1. What TRUQAP is and what it 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 inhibitor.

TRUQAP in combination with fulvestrant is used to treat adult patients with with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer that is advanced or that has spread to other parts of the body (metastatic), with an abnormal “PIK3CA”, “AKT1”, or “PTEN” gene, and whose cancer has progressed on or after endocrine therapy. Your healthcare provider will test your cancer for an abnormal “PIK3CA”, “AKT1”, or “PTEN” gene to make sure that TRUQAP is right for you.

TRUQAP is also used to treat menopausal women in combination with fulvestrant and another medicine called luteinizing hormone releasing hormone (LHRH) agonists.

For men with breast cancer, administration of LHRH agonist according to current clinical practice standards should be considered.

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.

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

**Do not use TRUQAP:**

- if you are hypersensitive (allergic) to Capivasertib or any of the other ingredients of TRUQAP (listed in section 6)

**Warnings and precautions**

Special care should be taken with TRUQAP if:

- 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 any current infections.
- 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 pregnant or plan to become pregnant. TRUQAP could harm your unborn baby. If you are able to become pregnant, you should use an effective method of contraception 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 and for 4 weeks after the last dose.
- You are a male with female partners who are or able to become pregnant. Male patients should use condoms and effective contraceptives 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 should read the full Patient Information Leaflet of fulvestrant for important information.
If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking TRUQAP.

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

• Signs of increased blood sugar levels (hyperglycaemia); increased thirst and dry mouth, passing urine more often than usual, 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.

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

**Other medicines and TRUQAP**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Some medicines may increase the risk of side effects of TRUQAP, for example:

- Certain antibiotics (eg. clarithromycin, telithromycin)
- Certain anti-fungals (eg. ketoconazole, itraconazole, voriconazole, posacinazole)
- Certain antivirals (eg. 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 with drinks**

Avoid intake of high doses of grapefruit juice while taking TRUQAP as it may increase side effects of TRUQAP.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Female patients: You should not fall pregnant while taking TRUQAP. 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 advise you to perform a pregnancy test during your treatment.

If you are able to become pregnant, you should use effective contraceptives during treatment with TRUQAP and for 4 weeks after the last dose. If you do become pregnant during the treatment, tell your doctor right away.

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.

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

**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.

**3. How to take TRUQAP**

Treatment with TRUQAP should be initiated and supervised by a medical practitioner experienced in the use of anticancer medicines.

Do not share medicines prescribed for you with any other person.

Always take TRUQAP exactly as your doctor has instructed you. You should check with your doctor if you are unsure. The TRUQAP dose is two 200 mg tablets taken twice a day (a total of 4 tablets each day) for four days followed by three days off treatment. Your doctor may prescribe a different dose if you are taking certain medicines that may interact with

TRUQAP (see section 3) or if you experience certain side effects while you are taking TRUQAP (see section 4). Your doctor will decide how long you stay on the treatment.

**Table 1 TRADENAME dosing schedule**

| | 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

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 tablets

Swallow TRUQAP tablets whole with water. Do no 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.

Take TRUQAP at about the same time in morning and evening of the dosing days. 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.

**If you take more TRUQAP than you should**

If you have taken more TRUQAP than you should, see a doctor or go to the nearest hospital straight away. Take the tablets and this leaflet with you.

**If you forget to take TRUQAP**

If you forget to take 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 2 doses to make up for a missed dose.

**If you stop taking TRUQAP**

Do not stop taking TRUQAP unless your doctor tells you. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

TRUQAP can have side effects.

Not all side effects reported for TRUQAP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRUQAP, please consult your health care provider for advice.

Immediately talk to your doctor 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.
- Signs of diarrhoea which may include loose or watery stool.
- 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.

**Frequent side effects**

- Urinary tract infection

- Decrease level of haemoglobin in blood
- High blood sugar level
- Loss of appetite
- Diarrhoea
- Nausea
- Vomiting
- Mouth sores or ulcers with gum inflammation (stomatitis)
- Rash
- Itching (pruritus)
- Tiredness
- Strange taste in the mouth (dysgeusia)
- Upset stomach, indigestion (dyspepsia)
- Drug eruptions
- Dry Skin
- Rash, skin reddening, blistering of lips, eyes or mouth, skin peeling (possible symptoms of Various skin conditions e.g., erythema multiforme)
- 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 12weeks)

**Less frequent side effects**

- Hypersensitivity
- Toxic Skin Eruptions
- Skin inflammation with rash (dermatitis)
- Shedding and/or scaling of skin surface (dermatitis exfoliative generalised)
- Diabetic ketoacidosis (a serious complication of high blood sugar level)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TRUQAP.

## 5. How to store TRUQAP

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store above 30 ºC.

Do not use TRUQAP if it is broken, cracked or otherwise not intact.

Return all unused medicine to your pharmacist.

Do not use TRUQAP after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.

## 6. Contents of the pack and other information

**What TRUQAP contains**

The active ingredient is capivasertib

The other ingredients are

*Tablet core:*

Microcrystalline cellulose

Dibasic calcium phosphate

Croscarmellose sodium

Magnesium stearate

*Tablet coating:*

Hypromellose

Titanium dioxide

Polyethylene glycol 3350

Polydextrose

Copovidone

Medium chain triglycerides

Yellow iron oxide

Red iron oxide

Black iron oxide

**What TRUQAP looks like and contents of the pack**

TRUQAP 160 mg tablets are round, biconvex, beige film-coated tablets marked with ‘CAV’ above ‘160’ on one side and plain on the reverse.

TRUQAP 200 mg tablets are capsule-shaped, biconvex, beige film-coated tablets marked with ‘CAV 200’ on one side and plain on the reverse.

TRUQAP is supplied in:

Aluminium/Aluminium blisters containing 16 film-coated tablets. The carton containing 4 blisters of 16 tablets each, 64 film-coated tablets.

**Holder of certificate of registration**

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West, Bryanston

Johannesburg, 2191

☎ (011) 797 6000

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**Registration Numbers**

TRUQAP 160 mg: 61/26/0291

TRUQAP 200 mg: 61/26/0292

**Access to the corresponding Professional Information**

For the latest Professional Information, kindly scan the QR code on the carton.

AstraZeneca Pharmaceuticals (Pty) Limited

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