

PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Truqap[®] 160 mg

Film coated tablets

Active ingredient:

Each Tablet contains:

Capivasertib 160 mg

Truqap[®] 200 mg

Film coated tablets

Active ingredient:

Each Tablet contains:

Capivasertib 200 mg

For inactive ingredients in the medicine - please see section 6 "Further Information".

Please see also section 2 – "Important information regarding some ingredients in the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT THE MEDICINE INTENDED FOR?

Truqap, in combination with fulvestrant, is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alteration as detected by an approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Therapeutic group

Truqap is a serine/threonine protein kinase inhibitor treatment that is able to specifically and potently inhibit the three isoforms of the AKT enzyme (AKT1/2/3).

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see section 6).

Special warnings regarding use of Truqap

Before treatment with Truqap, tell the doctor if:

- you have a history of high levels of sugar in your blood or diabetes
- you have a history of rash or other skin disorders
- you have liver problems.
- have any current infection.
- you are pregnant or plan to become pregnant. Truqap can harm your unborn baby. See section Pregnancy and breast-feeding.

Children and adolescents:

There is no information regarding the safety and efficacy of the use of this medicine in children and adolescents.

Tests and follow up

Your doctor will monitor your blood sugar levels before you start and during treatment with Truqap.

It is not known if Truqap is safe in people with type 1 diabetes or people who use insulin to treat their diabetes.

Your doctor will monitor your blood sugar levels more often if you have a history of diabetes, or if you are diabetic patient with risk factors for hyperglycemia, such as: obesity (BMI \geq 30), high level of sugar in the blood (higher than 160 mg/dL ($>$ 8.9 mmol/L)), hemoglobin A1C levels in the upper limit of normal or above, use of concomitant systemic corticosteroids, or intercurrent infections.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you take:

- CYP3A inhibitors strong or moderate, such as: itraconazole, erythromycin, verapamil increase capivasertib concentration in the blood, which may increase the risk of Truqap adverse reactions.
- CYP3A inducers strong or moderate, such as: rifampicin, efavirenz, decrease capivasertib concentration in the blood, which may reduce the effectiveness of Truqap.

Use of the medicine and food:

Avoid eating grapefruit or drinking grapefruit juice while taking Truqap.

You can take Truqap with or without food.

Pregnancy and breast-feeding:

Pregnancy

Tell your doctor if you are pregnant or planning to become pregnant. Truqap can harm your unborn baby.

Women in childbearing age:

- Your healthcare provider will check to see if you are pregnant before you start treatment with Truqap.

- You should use effective birth control during treatment with Truqap and for one month after the last dose. Talk to your doctor about birth control methods that may be right for you during this time.
- If you become pregnant or think you are pregnant, tell your doctor right away.

Male patients with female partners who are able to become pregnant should use effective birth control during the treatment with Truqap and for 4 months after the last dose. If your female partner becomes pregnant, tell your doctor right away.

Breastfeeding

Tell your doctor if you are breastfeeding or planned to breastfeed. Do not breastfeed during treatment with Truqap. Talk to your doctor about the best way to feed your baby during 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.

Important information regarding some ingredients in the medicine

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined by the doctor only.

The usual recommended dose is:

- Take Truqap 2 times each day (about 12 hours apart) in the morning and evening, at about the same times each day.
- Take Truqap for 4 days in a row, followed by 3 days not taking Truqap, each week.
- You can take Truqap with or without food.

- Swallow Truqap tablets whole with water. There is no information regarding chewing, halving, cutting or crushing the tablets.
- Do not take any tablets that are broken, cracked, or that look damaged.
- For women who have not reached menopause or are just starting menopause, your doctor will prescribe a medicine called a luteinizing hormone-releasing hormone (LHRH) agonist to take with Truqap and fulvestrant. For men, your healthcare provider may prescribe a LHRH agonist to take with TRUQAP and fulvestrant.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, immediately refer to the doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine:

If you miss a dose of Truqap, 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 2 doses at the same time to make up for a missed dose.

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

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Truqap may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects that require special attention

Tell your doctor straight away if you notice any of the following side effects:

Very common side effect (may affect more than 1 in every 10 patient):

- **High blood sugar levels (hyperglycemia)** - Hyperglycemia is common with Truqap and may be severe. Untreated severe hyperglycemia can lead to a condition called diabetic ketoacidosis that can happen in people treated with Truqap. Diabetic ketoacidosis is a serious condition that requires treatment in a hospital and that can lead to death. Your healthcare provider will monitor your blood sugar levels before you start and during treatment with Truqap. It is not known if Truqap is safe in people with type 1 diabetes or people who use insulin to treat their diabetes. Your healthcare provider will monitor your blood sugar levels more often if you have a history of diabetes. Tell your healthcare provider right away if you develop symptoms of hyperglycemia, including excessive thirst, dry mouth, more frequent urination than usual or a bigger amount of urine than normal, blurred vision, increased appetite with weight loss, abdominal pain, unusual tiredness, confusion, nausea, vomiting, fruity odor on breath, dry or flushed skin, difficulty breathing, sleepiness.
- **Diarrhea** – Diarrhea is very common during treatment with Truqap and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration). Tell your healthcare provider if you develop any signs of diarrhea, including loose or watery stool. Your healthcare provider will tell you to drink more fluids or take medicines to treat diarrhea.
- **Skin reactions** – Skin reactions are common with Truqap and can be severe. Tell your doctor or get medical help right away if you get a new or worsening rash, reddening of the skin, fever, blistering of the lips, eyes or mouth, blisters on the skin, skin peeling, itchiness or dry skin, eczema, a severe skin rash that causes blistering (erythema multiforme), skin discoloration, skin fissures, skin ulcers, urticaria, a skin rash that results from bleeding from small blood vessels (neems) into tissues (purpura).

Your doctor may tell you to decrease your dose, temporarily stop your treatment with Truqap, or completely stop your treatment with Truqap if you get certain serious side effects.

Other side effects:

Very common side effect (may affect more than 1 in every 10 patient) while taking Truqap include:

- decreased level of hemoglobin in the blood
- nausea
- tiredness
- vomiting
- mouth sores
- loss of appetite
- headache
- urinary tract infection
- kidney problems including rapid loss of kidney function (acute kidney injury)
- changes in certain blood tests: decreased leukocytes, lymphocytes and neutrophils, increased triglycerides
- 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)
- decreased level of potassium in the blood
- decreased level of platelets in the blood
- increased alanine aminotransferase level in the blood
- decreased calcium level in the blood

Common side effects (may affect 1-10 in every 100 people) while taking Truqap include:

- hypersensitivity (including anaphylactic reaction)
- anemia
- pneumonia
- pyrexia (fever)
- strange taste in mouth (dysgeusia)
- indigestion (dyspepsia)
- second malignancy

Uncommon side effects (may affect 1-10 in every 1000 people) while taking Truqap include:

- sepsis
- heart attack (acute myocardial infarction)

If a side effect appears, if any of the side effects worsen, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE TRUQAP?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who provided the medicine to you.
- Do not store different medicines in the same package.
- This medicine does not require any special temperature storage conditions. Storage at room temperature is recommended.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Cellulose, microcrystalline, Calcium hydrogen phosphate, Croscarmellose sodium, Magnesium stearate

Tablets coating:

Hypromellose, Copovidone, Titanium dioxide, Polydextrose, Macrogols 3350, medium-chain Triglycerides, Iron oxide yellow, Iron oxide red, Iron oxide black

What the medicine looks like and the content of the package

Truqap 160 mg:

beige, round, biconvex film-coated tablets marked with 'CAV' above '160' on one side and plain on the reverse.

Truqap 200 mg:

beige, capsule-shaped, biconvex film-coated tablets marked with 'CAV 200' on one side and plain on the reverse.

The package contains 4 blisters, 16 tablets in each blister. A total of 64 film coated tablets per pack.

Manufacturer: AstraZeneca AB, Södertälje, Sweden.

License Holder and importer:

AstraZeneca (Israel) Ltd., 1 Atirei Yeda St., Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Truqap 160 mg: 176-55-37770-99

Truqap 200 mg: 176-56-37771-99

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