

PATIENT INFORMATION

TRUQAP® (TRUE-cap)

(capivasertib)

tablets

What is TRUQAP?

TRUQAP is a prescription medicine used in combination with the medicine 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 (metastatic), with an abnormal “*PIK3CA*”, “*AKT1*”, or “*PTEN*” gene, and whose disease 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.

It is not known if TRUQAP is safe and effective in children.

Do not take TRUQAP if you:

Have had a severe allergic reaction to TRUQAP or are allergic to any of the ingredients of TRUQAP. See the end of this leaflet for a list of the ingredients in TRUQAP.

Before you take TRUQAP, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of high levels of sugar in your blood or diabetes.
- have a history of rash or other skin disorders.
- have liver problems.
- have any current infection.
- are pregnant or plan to become pregnant. TRUQAP can harm your unborn baby.

Females who are able to become pregnant:

- 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 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you during this time.
- If you become pregnant or think you are pregnant, tell your healthcare provider right away.

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

- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with TRUQAP. Talk to your healthcare provider about the best way to feed your baby during treatment with TRUQAP.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRUQAP may affect the way other medicines work, and other medicines may affect how TRUQAP works.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take TRUQAP?

- Take TRUQAP exactly as your healthcare provider tells you.
- Do not change your dose or stop taking TRUQAP unless your healthcare provider tells you.
- 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.
- Take TRUQAP with or without food.
- Swallow TRUQAP tablets whole with water. Do not chew, crush, or split the tablets.
- Do not take any tablets that are broken, cracked, or that look damaged.
- 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.
- For women who have not reached menopause or are just starting menopause, your healthcare provider 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.

What are the possible side effects of TRUQAP?

TRUQAP may cause severe side effects, including:

- **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
 - stomach area (abdominal) pain
 - unusual tiredness
 - confusion
 - nausea
 - vomiting
 - fruity odor on breath
 - dry or flushed skin
 - difficulty breathing
 - sleepiness
- **Diarrhea.** Diarrhea is 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 healthcare provider 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, or dry skin.

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

The most common side effects of TRUQAP include:

- nausea
- tiredness
- vomiting
- mouth sores
- changes in certain blood tests

These are not all of the possible side effects of TRUQAP. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

What should I avoid while taking TRUQAP?

- You should not drink grapefruit juice or eat grapefruit during treatment with TRUQAP.

How should I store TRUQAP?

- Store TRUQAP in original packaging at room temperature between 68°F to 77°F (20°C to 25°C).
- Throw away (discard) TRUQAP after 45 days if the tablets are not kept in the original packaging.
- TRUQAP comes in child resistant packaging.

Keep TRUQAP and all medicines out of the reach of children.

General information about the safe and effective use of TRUQAP.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TRUQAP for a condition for which it was not prescribed. Do not give TRUQAP to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TRUQAP that is written for health professionals.

What are the ingredients in TRUQAP?

Active ingredient: capivasertib.

Inactive ingredients: copovidone, croscarmellose sodium, dibasic calcium phosphate, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, polydextrose, polyethylene glycol 3350, and titanium dioxide

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For more information, go to <https://www.TRUQAP.com> or call 1-800-236-9933. If you still have questions, contact your healthcare provider.