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Truqap (*capivasertib*)

An overview of Truqap and why it is authorised in the EU

What is Truqap and what is it used for?

Truqap is a cancer medicine used in adults to treat breast cancer that is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body) when the cancer has come back or worsened after hormonal treatment. It is used when the cancer cells have receptors (targets) for certain hormones on their surface (ER-positive) and do not have large quantities of another receptor called HER2 (HER2-negative). The cancer cells must also have been shown to have one or more mutations (changes) in the *PIK3CA*, *AKT1* or *PTEN* genes. Truqap is used in combination with fulvestrant (an anti-oestrogen medicine).

If Truqap is used in women before the menopause or around the time of menopause (pre-menopausal or peri-menopausal), it should also be given in combination with a luteinising hormone-releasing hormone (LHRH) agonist (a medicine that lowers blood levels of the hormones oestrogen and progesterone).

Truqap contains the active substance capivasertib.

How is Truqap used?

Truqap can only be obtained with a prescription and treatment should be started by a doctor experienced in the use of cancer treatments.

Truqap is available as tablets to be taken twice a day, approximately 12 hours apart. The tablets are taken for four consecutive days, followed by three days with no treatment. Fulvestrant is given on days 1, 15 and 29, and once monthly thereafter.

Treatment with Truqap should continue for as long as the patient benefits from it; treatment may be stopped, or the dose reduced, if the patient has unacceptable side effects.

For more information about using Truqap, see the package leaflet or contact your doctor or pharmacist.

How does Truqap work?

The active substance in Truqap, capivasertib, blocks the activity of enzymes known as serine/threonine kinase (AKT) 1, 2 and 3. These enzymes play an important role in the growth and division of cancer

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cells with mutations in the *PIK3CA*, *AKT1* or *PTEN* genes. By blocking AKT1, AKT2 and AKT3, Truqap reduces the growth of cancer cells.

What benefits of Truqap have been shown in studies?

Truqap, used together with fulvestrant, was shown to slow down the growth and spread of breast cancer in one main study involving 708 adults with locally advanced or metastatic ER-positive and HER2-negative breast cancer whose disease came back or got worse after treatment with an aromatase inhibitor (a medicine that reduces oestrogen levels).

Patients received either Truqap or placebo (a dummy treatment) in combination with fulvestrant and the main measure of effectiveness was how long patients lived without the disease getting worse. In nearly half of the patients, the cancer cells had one or more *PIK3CA, AKT1* or *PTEN* mutations.

The study showed that in the group of patients with *PIK3CA, AKT1* or *PTEN* mutations, those treated with Truqap plus fulvestrant lived on average for 7.3 months without the disease getting worse, compared with 3.1 months for patients given placebo plus fulvestrant.

What are the risks associated with Truqap?

For the full list of side effects and restrictions with Truqap, see the package leaflet.

The most common side effects with Truqap (which may affect more than 1 in 10 people) include diarrhoea, rash, nausea (feeling sick), tiredness, vomiting, stomatitis (inflammation of the lining of the mouth), hyperglycaemia (high blood glucose levels), headache and decreased appetite.

The most common severe side effects were rash, diarrhoea, hyperglycaemia, hypokalaemia (low blood potassium levels), anaemia (low levels of red blood cells) and stomatitis.

Why is Truqap authorised in the EU?

Truqap, used together with fulvestrant, was shown to slow down the growth and spread of breast cancer in adults with locally advanced or metastatic ER-positive and HER2-negative breast cancer with one or more *PIK3CA, AKT1* or *PTEN* mutations.

Although patients treated with Truqap had more side effects than patients on placebo, the safety of Truqap in combination with fulvestrant was considered acceptable and manageable with standard care and dose modifications.

The European Medicines Agency therefore decided that Truqap's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Truqap?

The company that markets Truqap will conduct and submit the results of additional studies to further investigate the safety and effectiveness of the medicine, including in pre-menopausal women and in patients with diabetes, as the main study did not include patients with uncontrolled or insulin-dependent diabetes.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Truqap have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Truqap are continuously monitored. Suspected side effects reported with Truqap are carefully evaluated and any necessary action taken to protect patients.

Other information about Truqap

Truqap received a marketing authorisation valid throughout the EU on 17 June 2024.

Further information on Truqap can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/truqap.

This overview was last updated in 06-2024.