swissmedic

Summary report on authorisation dated 11 November 2024

Truqap® (active substance: capivasertib)

Authorisation in Switzerland: 19 March 2024

Film-coated tablets for the treatment of breast cancer

About the medicinal product

Truqap contains the active substance capivasertib. Truqap is used in combination with another medicinal product (fulvestrant) for the treatment of adult patients with hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer. The cancer in these patients is locally advanced or has spread to other parts of the body. Their cancer has also failed to respond to other anti-hormonal therapies. Furthermore, the cancer in these patients shows certain changes (mutations) in at least one of the genes PIK3CA, AKT1 or PTEN.

Worldwide, breast cancer is the leading cause of cancer-related deaths in women. The most common form of breast cancer is hormone receptor-positive (HR+) and HER2-negative (HER2-) breast cancer. Approximately 70% of all breast cancers are of this type.

Truqap was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are represented in Project Orbis.

Mode of action

Truqap is an "AKT kinase inhibitor". In many tumours, specific proteins called AKT kinases are hyperactivated in the cells. These proteins are used by the tumour cells to grow and multiply. The active substance capivasertib blocks the activity of these AKT kinases, thereby potentially reducing tumour growth and the spread of the cancer.

Use

Truqap is a prescription-only medicine. Truqap is available as a film-coated tablet in dosage strengths of 160 mg and 200 mg. The usual dose is two 200 mg tablets twice daily, on four consecutive days. Administration is then paused on days 5, 6 and 7. This administration schedule is repeated in a weekly cycle.

Efficacy

The efficacy of Truqap was investigated in the CAPItello-291 study, in which the patients were randomly assigned to receive either capivasertib combined with fulvestrant, or placebo (dummy drug) combined with fulvestrant. Of all the study participants, 155 patients in the capivasertib group and 134 subjects in the placebo group had tumours with mutations in PIK3CA, AKT1 or PTEN genes. In this subgroup there was a statistically detectable prolongation of median[1] progression-free survival (PFS)[2] in the capivasertib group of 7.3 months, compared to 3.1 months in the placebo group.

Precautions, undesirable effects, & risks

Truqap must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects are diarrhoea (72%), skin rash (41%), nausea (39%), tiredness (26%) and vomiting (23%).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Despite the numerous available treatment options, advanced breast cancer remains an incurable disease. There is an urgent medical need for new treatment options that improve patient survival and possess tolerable side effects.

The pivotal study showed a prolonged progression-free survival after capivasertib was administered in combination with fulvestrant in the investigated group of breast cancer patients with HR+ and HER2- tumours with modifications of their PIK3CA, AKT1 or PTEN genes.

Taking all the risks and precautions into account, and based on the available data, the benefits of Truqap outweigh the risks. Swissmedic has therefore authorised the medicinal product Truqap, containing the active substance capivasertib, for use in Switzerland.

[1] Median: the value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

[2] Progression-free survival (PFS): period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Truqap®

Information for patients (package leaflet): Information for patients Truqap®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.