swissmedic

Summary report on authorisation dated 4 July 2025

Tukysa® (active substance: tucatinib)

Indication extension in Switzerland: 11 March 2025

Film-coated tablets in combination with trastuzumab and capecitabine for the treatment of adults with metastatic HER2-positive breast cancer

About the medicinal product

Tukysa contains the active substance tucatinib and is used in combination with trastuzumab and capecitabine for the treatment of adults with metastatic HER2-positive breast cancer. Tukysa is indicated for patients who have received at least two prior anti-HER2 treatment regimens.

HER2 is the abbreviation for human epidermal growth factor receptor 2. These receptors trigger division of cancer cells. The breast cancer to be treated has already spread to other sites in the body (metastasised).

On 7 May 2020, Tukysa was first authorised by Swissmedic for the treatment, in combination with trastuzumab and capecitabine, of metastatic HER2-positive breast cancer in patients who have received at least two prior anti-HER2 therapies in any setting, including trastuzumab, pertuzumab and trastuzumab emtansine.

Mode of action

The active substance in Tukysa (tucatinib) is a tyrosine kinase inhibitor. Medicines in this group block the protein that controls how cells grow and divide, which helps stop the cancer cells from multiplying.

Use

Tukysa is available as a film-coated tablet in dosage strengths of 50 mg or 150 mg.

The recommended dose of Tukysa is 300 mg twice daily in 21-day cycles. The tablets should be swallowed whole, unchewed.

Tukysa is administered in combination with trastuzumab and capecitabine.

The treatment must be supervised by a doctor with experience in cancer treatment.

Efficacy

The efficacy of Tukysa in combination with trastuzumab and capecitabine was investigated in the HER2CLIMB study. The participating patients with locally advanced or metastatic HER2-positive breast cancer had previously received at least two treatments for HER2. The efficacy of Tukysa in combination with trastuzumab and capecitabine was compared with placebo (dummy drug) in combination with trastuzumab and capecitabine.

The results showed a significant improvement in progression-free survival. The patients in the Tukysa group had a lower risk of disease progression or death compared to the control group. On average, the time until the disease worsened was 7.6 months compared to 4.9 months in the placebo group.

Supporting data from the "real world" (real-world data, i.e. data not obtained from clinical trials) were also submitted.

Precautions, undesirable effects, & risks

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

The most common undesirable effect was diarrhoea, which also proved to be serious in some cases, associated with dehydration.

Vomiting and nausea were also often observed in patients taking Tukysa. Tukysa can also cause severe liver toxicity.

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

Metastatic breast cancer continues to be a fatal disease and the most frequent cause of cancer death in women.

The indication extension for Tukysa in combination with trastuzumab and capecitabine enables metastatic HER2-positive breast cancer to be treated after two prior anti-HER2 lines of treatment.

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

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tukysa®

Information for patients (package leaflet): Information for patients Tukysa®
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.