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Tukysa® (active substance: tucatinib)

First authorisation in Switzerland: 07.05.2020

Medicinal product (film-coated tablet) for the treatment of adult patients with metastatic HER2-positive breast cancer in combination with medicinal products containing the active substances trastuzumab and capecitabine

About the medicine

The medicinal product Tukysa, containing the active substance tucatinib, is a film-coated tablet authorised in Switzerland on 7 May 2020. Tukysa is used together with trastuzumab and capecitabine. It has been authorised for the treatment of metastatic HER2-positive breast cancer in patients who have received at least two prior anti-HER2 regimens, including trastuzumab, pertuzumab, and trastuzumab emtansine.

HER2-positive breast cancer is a type of breast cancer that tests positive for a protein called human epidermal growth factor receptor 2, which promotes the growth of cancer cells. If the cancer spreads outside the breast tissue or its draining lymph nodes, the cancer is called metastatic. Nearly half of HER2-positive breast cancer patients develop metastases in the brain over the course of their disease.

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 only on prescription. The treatment should be supervised by a physician experienced in administering anti-cancer medicines. Tukysa is available as either a 50 mg or 150 mg film-coated tablet.

The recommended dose of Tukysa is 300 mg taken orally twice daily in 21-day cycles. Tukysa is taken in combination with trastuzumab and capecitabine. Doses can be adjusted in the event of adverse reactions. The treatment schedule is described in the information for healthcare professionals.

Efficacy

The efficacy of Tukysa, with the active substance tucatinib, was investigated in a study called the HER2CLIMB study. All study participants had previously been treated with trastuzumab, pertuzumab, and trastuzumab emtansine and the disease had continued to progress.

The study included 612 adult patients, 410 of whom received tucatinib in combination with trastuzumab and capecitabine at standard doses, while 202 patients received a placebo in combination with trastuzumab and capecitabine at standard doses. Nearly half of the patients in the study had brain metastases (breast cancer cells in the brain) and nearly half had lung metastases (breast cancer cells in the lungs), among other organs where the disease had spread.

The study showed that patients who received the active ingredient tucatinib in combination with trastuzumab and capecitabine lived several months longer without their disease progressing compared to patients who received the placebo with trastuzumab and capecitabine.

Precautions, undesirable effects & risks

Tukysa may not be used if the patient is hypersensitive to the active ingredient tucatinib or any of the substances in the tablet, including colouring agents or preservatives.

Diarrhoea occurred in 81% of patients treated with Tukysa. Some of those cases included severe diarrhoea and associated dehydration, low blood pressure and acute fatal kidney failure. Tukysa can also cause severe liver toxicity. Other adverse effects, such as vomiting and nausea, occurred more often with Tukysa compared to placebo.

Women of childbearing age, or female partners of male patients, should use contraceptives during treatment with Tukysa and for one week after the last dose. There is no sufficient data on the use of Tukysa in pregnant women. Animal studies showed that Tukysa may be toxic to a foetus.

All precautions, risks and other possible undesirable effects are listed in the information for healthcare professionals.

Why the medicine has been authorised

Breast cancer is the most frequent cause of cancer death in women, and metastatic breast cancer remains a fatal disease.

Survival for HER2-positive metastatic breast cancer patients who have already received two lines of treatment is estimated at less than two years.

The study showed that patients with and without brain metastases benefited from Tukysa in combination with capecitabine and trastuzumab. Overall survival was 4.5 months longer than those in the placebo group. Adverse effects, such as diarrhoea, nausea and vomiting, increased with Tukysa. However, this toxicity was manageable.

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

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals – Tukysa®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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.