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Tukysa (*tucatinib*)

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

What is Tukysa and what is it used for?

Tukysa is a cancer medicine that is used to treat breast cancer that is locally advanced or metastatic (has spread to other parts of the body) and when it is HER2-positive. This means the cancer cells produce a protein on their surface, HER2, which stimulates the growth of the cancer.

Tukysa is used with two other medicines, capecitabine and trastuzumab, and is used after at least 2 other treatments for HER2-positive cancer have already been tried.

The active substance in Tukysa is tucatinib.

How is Tukysa used?

Tukysa can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in giving cancer treatments. It is given by mouth in a recommended dose of 300 mg twice a day. Patients are also treated with capecitabine and trastuzumab on certain days of a 21-day cycle.

Treatment can continue as long as the cancer does not get worse and side effects are bearable. The doctor may recommend a reduced dose of Tukysa if certain side effects occur, or may stop treatment temporarily or permanently.

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

How does Tukysa work?

The active substance in Tukysa, tucatinib, is a type of cancer medicine called a tyrosine kinase inhibitor. It attaches to the HER2 protein on the cancer cells, and so blocks its action. Because HER2 helps cancer cells to grow and divide, blocking it helps to stop these cells growing and causes them to die, controlling the growth of the cancer.

What benefits of Tukysa have been shown in studies?

Tukysa has been shown to improve the length of time that patients with advanced or metastatic HER2-positive breast cancer lived without their disease getting worse. In an ongoing main study involving

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612 such patients whose disease had got worse after previous treatments or in whom other treatments were unsuitable, Tukysa was compared with placebo (a dummy treatment) when added to two other cancer medicines, trastuzumab and capecitabine.

When the results were analysed, the average length of time that patients lived without their disease getting worse was 7.8 months with Tukysa and 5.6 months with placebo. Overall, around 41% of patients given Tukysa and 23% given placebo showed some response to treatment and the two groups lived on average about 22 months and 17 months respectively. Responses to Tukysa were comparable in the subgroup of patients whose cancer had spread to the brain.

What are the risks associated with Tukysa?

The most common side effects with Tukysa (which may affect more than 1 in 10 people) are nose bleeds, diarrhoea, nausea (feeling sick), vomiting, stomatitis (inflammation of the mouth), rash, arthralgia (joint pain), increases in the blood levels of liver enzymes ALT and AST (a sign of potential liver problems) and in bilirubin, and weight loss. The most common serious side effects with Tukysa (which may affect more than 1 in 20 people) are diarrhoea and increased ALT and AST; nausea and vomiting may also be serious.

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

Why is Tukysa authorised in the EU?

The European Medicines Agency noted that the evidence showed an improvement in survival with Tukysa in a group of patients who had few alternative options. The company would need to provide final results of the main study to clarify the exact extent of the benefits. The reported side effects were considered manageable, and mostly related to effects on the gut. The Agency therefore decided that Tukysa's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Tukysa will provide final results from the main study showing the length of time patients live overall as well as without their disease getting worse.

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

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

Other information about Tukysa

Tukysa received a marketing authorisation valid throughout the EU on 11 February 2021.

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

This overview was last updated in 02-2021.