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Teysuno (*tegafur/gimeracil/oteracil*)

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

What is Teysuno and what is it used for?

Teysuno is a cancer medicine. It belongs to a group of cancer medicines called fluoropyrimidines and is used to treat advanced gastric (stomach) cancer together with cisplatin (another cancer medicine). It is also used to treat metastatic colorectal cancer (cancer of the colon and rectum that has spread elsewhere in the body) in patients who can no longer be treated with other fluoropyrimidines because of unacceptable side effects. For this it may be used alone or with the cancer medicines oxaliplatin or irinotecan, with or without another medicine, bevacizumab.

Teysuno contains the active substances tegafur, gimeracil and oteracil.

How is Teysuno used?

Teysuno should only be prescribed by a doctor who is experienced in the use of cancer medicines.

Before starting treatment, it is recommended that patients are tested to check whether they have a working dihydropyrimidine dehydrogenase (DPD) enzyme.

Teysuno is available as capsules containing 15 mg tegafur with 4.35 mg gimeracil and 11.8 mg oteracil, and as capsules containing 20 mg tegafur with 5.8 mg gimeracil and 15.8 mg oteracil. The recommended initial dose depends on the patient's height and weight. Teysuno capsules should be taken at least one hour before or after a meal.

For the treatment of advanced gastric cancer, Teysuno is used in a four-week cycle starting on the day of cisplatin administration. The capsules are given twice daily for 21 days followed by a 7-day gap before the next course. Cisplatin treatment stops after six cycles, but Teysuno treatment is continued unless the disease gets worse or the side effects are unacceptable.

For the treatment of metastatic colorectal cancer, Teysuno is used in a three-week cycle, with capsules given twice daily for 14 days, followed by a 7-day gap before starting the next cycle. Bevacizumab can be given on day 1 of each cycle. If Teysuno is given in combination with oxaliplatin and irinotecan, a lower dose is recommended.

Doses need to be adjusted for patients with kidney disease and for patients who develop certain side effects. For patients with partial DPD deficiency, a lower starting dose may be considered.

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

How does Teysuno work?

The main active substance in Teysuno, tegafur, is a cytotoxic medicine (a medicine that kills rapidly dividing cells, such as cancer cells). Tegafur is converted to the medicine fluorouracil in the body, but more is converted in tumour cells than in normal tissues.

Fluorouracil is very similar to pyrimidine. Pyrimidine is part of the genetic material of cells (DNA and RNA). In the body, fluorouracil takes the place of pyrimidine and interferes with the enzymes involved in making new DNA. As a result, it prevents the growth of tumour cells and eventually kills them.

The two other active substances in Teysuno allow tegafur to be effective at lower doses and with fewer side effects: gimeracil by preventing the breakdown of fluorouracil and oteracil by reducing the activity of fluorouracil in normal, non-cancerous tissue in the gut.

What benefits of Teysuno have been shown in studies?

Gastric cancer

Teysuno has been shown to be as effective as fluorouracil in the treatment of advanced gastric cancer in clinical trials. In a main study, Teysuno was compared with the cancer medicine fluorouracil given as an infusion in 1,053 adults with advanced gastric cancer. Both medicines were given with cisplatin. The main measure of effectiveness was how long the patients lived.

Treatment with Teysuno capsules was as effective as treatment with fluorouracil infusions. Patients receiving Teysuno with cisplatin lived for an average of 8.6 months compared with 7.9 months for patients receiving fluorouracil with cisplatin.

Colorectal cancer

The company presented results from retrospective cohort studies in which Teysuno was used to treat metastatic colorectal cancer, after patients had experienced unacceptable side effects with other fluoropyrimidine-based treatments. In addition, the company provided a review and analysis of studies from the scientific literature in which Teysuno treatment was compared to other fluoropyrimidines for the treatment of metastatic colorectal cancer. In total, 1,062 patients treated with Teysuno-based therapies and 1,055 patients who were treated with other fluoropyrimidine-based treatments were included in this analysis. The analysis showed that both the time patients lived without their disease worsening and the time patients lived overall were comparable between patients treated with Teysuno and patients treated with other medication.

What are the risks associated with Teysuno?

In patients with advanced gastric cancer treated with Teysuno in combination with cisplatin, the most common severe side effects (which may affect more than 1 patient in 10) are neutropenia (low levels of neutrophils, a type of white blood cell), anaemia (low red blood cell counts) and fatigue (tiredness).

In patients with metastatic colorectal cancer, side effects appear similar to those seen in patients treated for advanced gastric cancer.

Teysuno must not be used in the following groups:

- patients currently receiving another fluoropyrimidine (a group of anticancer medicines that includes Teysuno) or who have had severe and unexpected reactions to fluoropyrimidine therapy;
- patients known to have no DPD enzyme activity, as well as patients who, within the previous four weeks, have been treated with a medicine that blocks this enzyme;
- pregnant or breastfeeding women;
- patients with severe leucopenia, neutropenia, or thrombocytopenia (low levels of white cells or platelets in the blood);
- patients with severe kidney problems requiring dialysis;
- patients who should not be receiving cisplatin, oxaliplatin, irinotecan or bevacizumab.

For the full list of all side effects and restrictions of Teysuno, see the package leaflet.

Why is Teysuno authorised in the EU?

Teysuno, in combination with cisplatin, has been shown to be effective in treating gastric cancer, and analysis of the literature has shown Teysuno-based treatments to be effective for metastatic colorectal cancer in patients for whom other fluoropyrimidine-based regimens are not an option because of side effects. The safety profile of the medicine is considered acceptable. The European Medicines Agency therefore decided that Teysuno'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 Teysuno?

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

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

Other information about Teysuno

Teysuno received a marketing authorisation valid throughout the EU on 14 March 2011.

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

This overview was last updated in 01-2022.