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Tabrecta (*capmatinib*)

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

What is Tabrecta and what is it used for?

Tabrecta is a medicine used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC), when the cancer is advanced and its cells have particular genetic mutations (changes) leading to 'mesenchymal-epithelial transition factor gene exon 14 (METex14) skipping'. This means that the cancer cells make an abnormal form of a protein called MET, because a part of the MET gene known as exon 14 is not used.

Tabrecta is used when the patient needs further treatment after receiving immunotherapy or platinum-based chemotherapy, or both.

Tabrecta contains the active substance capmatinib.

How is Tabrecta used?

Tabrecta can only be obtained with a prescription and treatment should be started and supervised by a doctor with experience in using cancer medicines.

Before starting treatment, the patients should have tests to confirm the METex14 skipping mutations in their cancer.

Tabrecta is available as tablets to be taken by mouth. The recommended dose is 400 mg twice per day. Treatment with Tabrecta can continue for as long as the patient benefits from it. If certain side effects develop, the doctor may decide to reduce the dose, or to interrupt or stop treatment with Tabrecta.

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

How does Tabrecta work?

The MET protein belongs to a family of enzymes called receptor tyrosine kinases, which are involved in the growth of cells. In NSCLC patients with 'METex14 skipping', an abnormal form of the MET protein is produced that causes cancer cells to divide and grow in an uncontrolled fashion.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The active substance in Tabrecta, capmatinib, is a receptor tyrosine kinase inhibitor that attaches to this abnormal MET protein inside cancer cells. This stops the effect of MET, helping to slow down the growth and spread of the cancer.

What benefits of Tabrecta have been shown in studies?

The effect of Tabrecta was investigated in a main study involving 100 patients with advanced NSCLC with a 'METex14 skipping' mutation and whose disease had progressed after previously being treated with immunotherapy with or without platinum-based chemotherapy. Response to treatment (shrinkage in the size of the cancer) was assessed using body scans and 44% of the patients showed partial or complete cancer shrinkage after being treated with Tabrecta. On average, the response lasted for at least 10 months.

In this study, Tabrecta was not compared with any other treatment for NSCLC or with placebo (dummy treatment).

What are the risks associated with Tabrecta?

The most common side effects with Tabrecta (which may affect more than 1 in 5 people) are peripheral oedema (swelling especially of the hands, ankles or feet), nausea (feeling sick), tiredness, an increase in creatinine levels in the blood (a sign of kidney problems), vomiting, difficulty breathing, decreased appetite and back pain.

The most common serious side effects with Tabrecta are difficulty breathing, interstitial lung disease (a disorder causing scarring in the lungs) and pneumonitis (inflammation in the lungs), cellulitis (inflammation of the deep skin tissue), peripheral oedema and increased levels in the blood of a liver enzyme called alanine aminotransferase (ALT), as well as of amylase and/or lipase (a sign of pancreatic problems).

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

Why is Tabrecta authorised in the EU?

Although the main study did not compare Tabrecta with another cancer treatment, it showed that this medicine is effective in previously treated patients with NSCLC whose cancer was advanced and had the 'METex14 skipping' mutation. The side effects of Tabrecta were considered manageable.

The European Medicines Agency therefore decided that Tabrecta'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 Tabrecta?

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

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

Other information about Tabrecta

Tabrecta received a marketing authorisation valid throughout the EU on 20 June 2022

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

This overview was last updated in 07-2022.