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Tepmetko (*tepotinib*)

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

What is Tepmetko and what is it used for?

Tepmetko is a cancer medicine that is used to treat adults with 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.

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

Tepmetko contains the active substance tepotinib.

How is Tepmetko used?

The medicine can only be obtained with a prescription, and treatment should be started and supervised by a doctor who is experienced in using cancer medicines.

The patient's cancer should be tested before starting treatment to confirm METex14 skipping mutations.

Tepmetko is available as tablets and is taken by mouth. The recommended dose is 450 mg once per day. Treatment can continue until the patient no longer benefits from it. If certain side effects develop, the doctor may decide to reduce the dose to 225 mg once per day, or to interrupt or stop treatment with Tepmetko.

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

How does Tepmetko 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. The active substance in Tepmetko, tepotinib, is a receptor tyrosine kinase inhibitor that attaches to this abnormal MET

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protein inside cancer cells. This stops the effect of MET, helping to slow down the growth and spread of the cancer.

What benefits of Tepmetko have been shown in studies?

In one main study involving 138 patients, Tepmetko was effective in treating adults with NSCLC with METex14 skipping mutations whose disease had progressed after previously being treated with other cancer medicines. Tepmetko was not compared with any other treatment or placebo (dummy treatment).

Response to treatment (shrinkage in the size of the cancer) was assessed using body scans. Around 44% (61 out of 138) of the patients showed partial or complete cancer shrinkage after treatment with Tepmetko. On average, responses lasted for over 11 months.

What are the risks associated with Tepmetko?

The most common side effects with Tepmetko (which may affect more than 1 in 5 people) are oedema (build-up of fluid), nausea (feeling sick), low albumin level in the blood, diarrhoea, and increase in creatinine level in the blood (a sign of kidney problems). The most common serious side effects with Tepmetko (which may affect more than 1 in 100 people) are peripheral oedema (swelling especially of the ankles and feet), generalised oedema (build-up of fluid in the whole body) and interstitial lung disease (disorder causing scarring in the lungs).

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

Why is Tepmetko authorised in the EU?

There are currently no specific treatment options for patients with advanced NSCLC with METex14 skipping mutations. Although the main study did not compare Tepmetko with another cancer treatment, it showed that the medicine was effective in patients whose cancer had progressed after several different treatments. In general, Tepmetko's side effects were considered manageable.

The European Medicines Agency therefore decided that Tepmetko'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 Tepmetko?

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

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

Other information about Tepmetko

Tepmetko received a marketing authorisation valid throughout the EU on 16 February 2022.

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

This overview was last updated in 02-2022.