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Tabrecta® (active substance: capmatinib)

Temporary authorisation in Switzerland: 26 April 2021

Medicinal product (film-coated tablets) for the treatment of non-small cell lung cancer (NSCLC) with MET exon 14 skipping mutations.

About the medicinal product

Tabrecta is a cancer treatment containing the active substance capmatinib.

Tabrecta is used to treat adults with a kind of lung cancer called "non-small cell lung cancer" (NSCLC).

The treatment is given to patients whose lung cancer has spread to other parts of the body (metastatic) and who possess a change (mutation) in a gene that makes an enzyme called MET receptor tyrosine kinase. The genetic mutation in these patients is known as a MET exon 14 skipping mutation.

Since this is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements.

Mode of action

Tabrecta acts as an inhibitor of MET receptor tyrosine kinase, whose production is increased in this type of cancer.

By blocking this protein (enzyme), Tabrecta curbs the growth and spread of the cancer.

Use

Tabrecta is a prescription-only medicine authorised as a film-coated tablet at the dosage strengths of 150 mg and 200 mg.

Tabrecta may only be used if a specific mutation of the MET gene is detected: MET exon 14 skipping mutation.

The recommended dose is 400 mg twice daily. Tabrecta may be taken with or without food (independently of meals). The film-coated tablets may not be broken, chewed or crushed.

Treatment with Tabrecta has not been investigated in children or adolescents.

Efficacy

The efficacy of Tabrecta was investigated in an open-label study (A2201) with 69 subjects who had already received previous cancer treatment and patients (28 subjects) who had not received any previous treatment, all of whom possessed a MET exon 14 skipping mutation.

The patients received 400 mg Tabrecta twice daily until either the disease progressed or they had to stop taking the drug due to side effects. The objective overall response rate (ORR) was measured. This shows the percentage of patients experiencing a tumour reduction. Overall survival while taking Tabrecta was another outcome recorded in the study. The overall survival refers to the period between the start of treatment and the death of the patient.

The 28 previously untreated patients showed an ORR of 68%, compared to 41% in the previously treated group. The median[1] overall survival was 21 months in the previously untreated group and 14 months in the previously treated group.

Precautions, undesirable effects & risks

Tabrecta must not be used in those who are hypersensitive to the active substance or any of the excipients.

Tabrecta may cause side effects, which must be reported to the doctor without delay.
The most common serious side effects in patients treated with Tabrecta are changes in certain blood tests, cough, fever, trouble breathing, shortness of breath or wheezing, which can be signs of inflammation of the lungs (pneumonitis, interstitial lung disease) and kidney problems.

During treatment with Tabrecta, exposure to the sun or artificial ultraviolet (UV) light should be avoided.

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

The disease of metastatic NSCLC has a fatal outcome in all cases. Specific treatment with Tabrecta, the MET tyrosine kinase inhibitor capmatinib, can control the disease for a certain period.

In the efficacy study described above, a clinically significant overall response rate, which was higher than what can be expected from existing authorised medicines according to the historical data, was observed during the first treatment with Tabrecta for MET exon 14 skipping mutation-positive NSCLC.

Based on all the available data, the benefits of Tabrecta outweigh the risks. The medicinal product Tabrecta with the active substance capmatinib has been authorised temporarily in Switzerland for the treatment of adult patients with MET exon 14 skipping NSCLC (Art. 9a TPA) since not all clinical studies had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the

[1] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

temporary authorisation can be converted into an ordinary authorisation.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tabrecta®

Information for patients (package leaflet): Information for patients Tabrecta®

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

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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