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EPAR summary for the public

Temozolomide Teva

temozolomide

This is a summary of the European public assessment report (EPAR) for Temozolomide Teva. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Temozolomide Teva.

What is Temozolomide Teva?

Temozolomide Teva is a medicine that contains the active substance temozolomide. It is available as capsules (5, 20, 100, 140, 180 and 250 mg).

Temozolomide Teva is a 'generic medicine'. This means that Temozolomide Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Temodal. For more information on generic medicines, see the question-and-answer document here.

What is Temozolomide Teva used for?

Temozolomide Teva is a cancer medicine. It is used to treat malignant glioma (brain tumours) in the following groups of patients:

- adults with newly diagnosed glioblastoma multiforme (an aggressive type of malignant glioma). Temozolomide Teva is used first with radiotherapy and then on its own;
- adults and children three years of age and over with malignant glioma such as glioblastoma multiforme or anaplastic astrocytoma, when the tumour has returned or got worse after standard treatment. Temozolomide Teva is used on its own in these patients.

The medicine can only be obtained with a prescription.

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How is Temozolomide Teva used?

Treatment with Temozolomide Teva should be prescribed by a doctor with experience in the treatment of brain tumours.

The dose of Temozolomide Teva depends on body surface area (calculated using the patient's height and weight) and ranges from 75 to 200 mg per square metre, once a day. The dose and the number of doses depend on the type of tumour being treated, whether the patient has been treated before, whether Temozolomide Teva is being used alone or with other treatments, and how the patient responds to treatment. Temozolomide Teva should be taken without food.

Patients may also need to take medicines to prevent vomiting before taking Temozolomide Teva. Temozolomide Teva should be used with caution in patients with severe liver problems or with kidney problems.

For full details, see the summary of product characteristics (also part of the EPAR).

How does Temozolomide Teva work?

The active substance in Temozolomide Teva, temozolomide, belongs to a group of cancer medicines called alkylating agents. In the body, temozolomide is converted to another compound called MTIC. MTIC binds to the DNA of cells while they are reproducing, which stops cell division. As a result, the cancer cells cannot divide, slowing down the growth of tumours.

How has Temozolomide Teva been studied?

Because Temozolomide Teva is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Temodal. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Temozolomide Teva?

Because Temozolomide Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine.

Why has Temozolomide Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Temozolomide Teva has been shown to have comparable quality and to be bioequivalent to Temodal. Therefore, the CHMP's view was that, as for Temodal, the benefit outweighs the identified risk. The Committee recommended that Temozolomide Teva be given marketing authorisation.

Other information about Temozolomide Teva

The European Commission granted a marketing authorisation valid throughout the EU for Temozolomide Teva on 28 January 2010.

The full EPAR for Temozolomide Teva can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Temozolomide Teva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 07-2014.