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EPAR summary for the public

Temozolomide Sandoz

temozolomide

This is a summary of the European Public Assessment Report (EPAR) for Temozolomide Sandoz. 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 Sandoz.

What is Temozolomide Sandoz?

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

Temozolomide Sandoz is a 'generic medicine'. This means that Temozolomide Sandoz 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 Sandoz used for?

Temozolomide Sandoz is an anticancer 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 brain tumour). Temozolomide Sandoz 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 Sandoz is used on its own in these patients.

The medicine can only be obtained with a prescription.

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How is Temozolomide Sandoz used?

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

The dose of Temozolomide Sandoz 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 Sandoz is being used alone or with other treatments, and how the patient responds to treatment. Temozolomide Sandoz should be taken without food.

Patients may also need to take medicines to prevent vomiting before taking Temozolomide Sandoz.

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

How does Temozolomide Sandoz work?

The active substance in Temozolomide Sandoz, temozolomide, belongs to a group of anticancer 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 Sandoz been studied?

Because Temozolomide Sandoz is a generic medicine, studies in people 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 benefit and risk of Temozolomide Sandoz?

Because Temozolomide Sandoz is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Temozolomide Sandoz been approved?

The CHMP concluded that, in accordance with EU requirements, Temozolomide Sandoz 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 Sandoz be given marketing authorisation.

Other information about Temozolomide Sandoz

The European Commission granted a marketing authorisation valid throughout the European Union for Temozolomide Sandoz on 15 March 2010.

The full EPAR for Temozolomide Sandoz 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 Sandoz, 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 10-2014.