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EPAR summary for the public

Temozolomide Hexal

temozolomide

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

What is Temozolomide Hexal?

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

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

Temozolomide Hexal 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 Hexal 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 Hexal is used on its own in these patients.

The medicine can only be obtained with a prescription.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How is Temozolomide Hexal used?

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

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

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

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

How does Temozolomide Hexal work?

The active substance in Temozolomide Hexal, 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 Hexal been studied?

Because Temozolomide Hexal 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 Hexal?

Because Temozolomide Hexal 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 Hexal been approved?

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

Other information about Temozolomide Hexal

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

The full EPAR for Temozolomide Hexal 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 Hexal, 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.