EMA/84099/2012
EMEA/H/C/000229

EPAR summary for the public

Temodal

temozolomide

This is a summary of the European public assessment report (EPAR) for Temodal. 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 Temodal.

What is Temodal?

Temodal is a medicine that contains the active substance temozolomide. It is available as capsules (5 mg, 20 mg, 100 mg, 140 mg, 180 mg and 250 mg) and as a powder to be made up into a solution for infusion (drip into a vein).

What is Temodal used for?

Temodal 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). Temodal 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. Temodal is used on its own in these patients.

The medicine can only be obtained with a prescription.

How is Temodal used?

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The dose of Temodal 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 Temodal is being used alone or with radiotherapy, and how the patient responds to treatment. Temodal capsules should be taken whole without food. If the solution for infusion is used, it should be given over a period of 90 minutes. Patients may also need to take medicines to prevent vomiting before taking Temodal.

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

How does Temodal work?

The active substance in Temodal, 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 Temodal been studied?

Temodal capsules have been studied in four main studies.

The first study compared the effectiveness of Temodal and radiotherapy with that of radiotherapy on its own in 573 patients with newly diagnosed glioblastoma multiforme.

The other three main studies involved patients with malignant glioma that had come back or got worse after previous treatment. Two of these studies involved patients with glioblastoma multiforme: one looked at the effects of Temodal in 138 patients and the other compared Temodal with procarbazine (another anticancer medicine) in 225 patients. The final study looked at the safety and effectiveness of Temodal in the treatment of 162 patients with anaplastic astrocytoma who were in their first relapse.

The main measures of effectiveness were how long the patients survived or the length of time before the patient's cancer started to get worse.

A further two studies were carried out in a total of 35 patients with brain tumours to show that the capsules and solution for infusion produce the same levels of temozolomide in the blood.

What benefit has Temodal shown during the studies?

In the study of newly diagnosed glioblastoma multiforme, patients survived for an average of 14.6 months when they received Temodal and radiotherapy, compared with 12.1 months with radiotherapy alone.

In the comparative study of glioblastoma multiforme that had come back or got worse after previous treatment, it took an average of 2.9 months until the cancer got worse in patients taking Temodal, compared with 1.9 months in the patients taking procarbazine. In anaplastic astrocytoma, it took an average of 5.4 months for the cancer to get worse in patients taking Temodal.

What is the risk associated with Temodal?

The most common side effects with Temodal (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, constipation, loss of appetite, alopecia (hair loss), headache, fatigue (tiredness), convulsions (fits), rash, neutropenia or lymphopenia (low white blood cell counts), and thrombocytopenia (low blood platelet counts). Patients receiving the solution for infusion may also

have injection site reactions, such as pain, irritation, itching, warmth, swelling and redness, as well as bruising. For the full list of all side effects reported with Temodal, see the package leaflet.

Temodal must not be used in people who are hypersensitive (allergic) to temozolomide, any of the other ingredients or dacarbazine (another anticancer medicine). Temodal must not be used in patients with severe myelosuppression (a condition in which the bone marrow cannot make enough blood cells).

Why has Temodal been approved?

The CHMP decided that Temodal's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Temodal

The European Commission granted a marketing authorisation valid throughout the European Union for Temodal on 26 January 1999.

The full EPAR for Temodal 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 Temodal, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2012.