



EMA/329022/2015
EMA/H/C/001125

EPAR summary for the public

Temozolomide Accord¹

temozolomide

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

What is Temozolomide Accord?

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

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

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

The medicine can only be obtained with a prescription.

How is Temozolomide Accord used?

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

¹ Previously known as Temozolomide Hospira.



The dose of Temozolomide Accord 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 Accord is being used alone or with other treatments, and how the patient responds to treatment. Temozolomide Accord should be taken without food. Patients may also need to take medicines to prevent vomiting before taking Temozolomide Accord.

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

How does Temozolomide Accord work?

The active substance in Temozolomide Accord, 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 Accord been studied?

Because Temozolomide Accord 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 Accord?

Because Temozolomide Accord 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 Accord been approved?

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

Other information about Temozolomide Accord:

The European Commission granted a marketing authorisation valid throughout the EU for Temozolomide Hospira on 15 March 2010. The name of the medicine was changed to Temozolomide Accord on 27 May 2015.

The full EPAR for Temozolomide Accord 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 Accord, 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 05-2015.