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Public statement

Temozolomide Sandoz (temozolomide)

Withdrawal of the marketing authorisation in the European Union

On 15 September 2022, the European Commission withdrew the marketing authorisation for Temozolomide Sandoz (temozolomide) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Sandoz GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Temozolomide Sandoz was granted marketing authorisation in the EU on 15 March 2010 for treatment of:

- adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment,
- children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2014.

Temozolomide Sandoz is a generic medicine of Temodal. There are other generic medicinal products of Temodal authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Temozolomide Sandoz will be updated to indicate that the marketing authorisation is no longer valid.

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