



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2018
EMA/88410/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Carmustine Obvius

carmustine

On 26 April 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Carmustine Obvius, intended for the treatment of brain tumours, non-Hodgkin's lymphoma and Hodgkin's disease. The applicant for this medicinal product is Obvius Investment B.V.

Carmustine Obvius will be available as a 100-mg powder and solvent for solution for infusion. The active substance of Carmustine Obvius is carmustine, an alkylating antineoplastic agent of the nitrosourea type (ATC code: L01AD01), which prevents DNA replication and transcription by alkylating reactive sites on nucleoproteins.

Carmustine Obvius is a generic of Carmubris which has been authorised in the EU since 31 July 1996. Since Carmustine Obvius is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Carmubris was not required. A question and answer document on generic medicines can be found [here](#).

The full indication is: "in the treatment of new or recurrent brain tumors - glioblastoma, medulloblastoma, astrocytoma and metastatic brain tumors; Second line treatment of non-Hodgkin's lymphomas and Hodgkin's disease". It is proposed that Carmustine Obvius be prescribed by physicians experienced in the treatment of cancer.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

