

Carmustine (Carmustine Obvius®) as conditioning treatment before transplantation in patients with Hodgkin's lymphoma (HL) and non-Hodgkin's lymphomas (NHL)

General information

Drug description [1]

Carmustine is a cell-cycle phase nonspecific antineoplastic agent of the nitrosourea type, which exerts tumor cytotoxicity via multiple mechanisms. As an alkylating agent, it can alkylate reactive sites on nucleoproteins, thus interfering with DNA and RNA synthesis and DNA repair. It is able to form interstrand crosslinks in DNA, which prevents DNA replication and transcription.

Indication [2]

Carmustine is used as a conditioning treatment before transplantation of the patient's own haematopoietic progenitor cells to treat HL and NHL

Current treatment [3]

- ❖ Several treatment options are authorised in the EU for patients undergoing HSCT, including radiation treatment or intensive treatment with cancer medicines such as busulfan to clear the bone marrow of existing cells in preparation for HSCT.
- ❖ The choice of conditioning regimen varies and is typically based on institutional experience.
- ❖ The most frequently used intensive chemotherapy cited in the literature is a combination of carmustine, etoposide, cytarabine and melphalan (BEAM)
- ❖ BEAM regimen is considered the regimen of choice for patients with HL and NHL submitted to ASCT, due to its acceptable safety profile and a quite high antitumor efficacy.

Regulatory status

EMA [1]

Approval status for this indication: approved

Other indications:

- ❖ Carmustine is effective in the following malignant neoplasms as a single agent or in combination with other antineoplastic agents and/or other therapeutic measures (radiotherapy, surgery):
 - Brain tumours (glioblastoma, Brain-stem gliomas, medulloblastoma, astrocytoma and ependymoma), brain metastases
 - Secondary therapy in NHL and Hodgkin's disease

✓ **Generic medicine:** Carmustine Obvius contains the same active substance and works in the same way as a reference medicine already authorised in the EU called Carmubris®.

FDA [4]

Approval status for this indication: not approved

Other indications:

- ❖ BiCNU® is indicated as palliative therapy as a single agent or in established combination therapy with other approved chemotherapeutic agents in the following:
 - Brain tumours glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumours
 - Multiple myeloma - in combination with prednisone
 - Relapsed or refractory HL in combination with other approved drugs
 - Relapsed or refractory NHL in combination with other approved drugs

Costs

Currently, there is **no cost information** for Carmustine Obvius available.

Carmubris® 100 mg = € 948.00 (ex-factory price) [5]

Posology [1]

Carmustine® is given in combination with other chemotherapeutic agents in patients with malignant haematological diseases before HPCT at a dose of 300 - 600 mg/m² intravenously.

Additional information (EMA)[2]

- ❖ Studies on the benefits and risks of the active substance carmustine in the authorised uses as cancer medicine have already been carried out with the reference medicine (Carmubris®) and do not need to be repeated for Carmustine Obvius.
- ❖ For use as a conditioning treatment (as Carmubris®) is not authorised for this use, the company provided data from the medical literature
- ❖ Further information: [Carmustine Obvius Assessment report](#) [3]

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Abbreviations: AE=adverse event, AJ=adjustment, ASCT=autologous stem cell transplantation, C=comparator, CI=confidence interval, DNA=deoxyribonucleic acid, EMA=European Medicines Agency, FDA=Food and Drug Administration, HL=Hodgkin's lymphoma, HPCT=haematopoietic progenitor cell transplantation, HSCT=haematopoietic stem cell transplantation, NHL=non-Hodgkin's lymphoma, RNA=ribonucleic acid

References:

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3. European Medicines Agency (EMA). Carmustine Obvius: EPAR - Assessment Report [Available from: https://www.ema.europa.eu/en/documents/variation-report/carmustine-obvius-h-c-4326-ii-0002-epar-assessment-report-variation_en.pdf].
4. U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA-approved drugs. Carmustine [Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017422s05lbl.pdf].
5. Österreichischer Apotheker-Verlag. Warenverzeichnis Online [Available from: <https://warenverzeichnis.apoverlag.at/>].