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Carmustine medac[1] (*carmustine*)

An overview of Carmustine medac and why it is authorised in the EU

What is Carmustine medac and what is it used for?

Carmustine medac is a cancer medicine that is used, on its own or with other cancer medicines and treatments, to treat the following types of cancer:

- brain tumours, both those that develop directly in the brain and cancers that have spread from elsewhere in the body (metastatic brain tumours);
- Hodgkin's lymphoma and non-Hodgkin's lymphomas, types of cancer that originate from white blood cells. The medicine is used when initial treatment has not worked or the cancer has come back;
- tumours of stomach and bowel;
- malignant melanoma (a type of skin cancer).

Carmustine medac is also used as a 'conditioning' treatment before transplantation of the patient's own haematopoietic progenitor cells (immature cells that are able to produce the cells of the blood) to treat Hodgkin's lymphoma and non-Hodgkin's lymphomas. It is used to clear the patient's bone marrow and make room for the transplanted cells.

Carmustine medac contains the active substance carmustine and is a 'generic medicine'. This means that Carmustine medac contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Carmubris. For more information on generic medicines, see the question-and-answer document here.

[1] Previously known as Carmustine Obvius

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

How is Carmustine medac used?

Carmustine medac is given by infusion (drip) into a vein. It must be given under the supervision of a doctor experienced in the use of cancer medicines and can only be obtained with a prescription. For the treatment of cancer, a dose based on the patient's weight and height is given at intervals of at least 6 weeks, and should be adjusted according to the patient's blood cell counts.

When used as a conditioning treatment, Carmustine medac is given before the cell transplant.

For more information about using Carmustine medac, see the package leaflet or contact your doctor or pharmacist.

How does Carmustine medac work?

Carmustine, the active substance in this medicine, is a type of cancer medicine known as an alkylating agent. It interferes with the normal function and repair of DNA and RNA, the genetic instructions that cells need to function and multiply. Because cancer cells tend to grow and multiply more than normal cells they are more vulnerable to the action of the medicine. By damaging the DNA of cancer cells, carmustine can help kill them and prevent the cancer from growing and spreading. When used as a conditioning treatment carmustine helps clear the patient's bone marrow cells as they multiply more quickly than normal cells and are therefore more vulnerable to the action of the medicine.

How has Carmustine medac been studied?

Studies on the benefits and risks of the active substance carmustine in the authorised uses as a cancer medicine have already been carried out with the reference medicine, Carmubris, and do not need to be repeated for Carmustine medac.

As for every medicine, the company provided studies on the quality of Carmustine medac. There was no need for 'bioequivalence' studies to investigate whether Carmustine medac is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Carmustine medac is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

For use as a conditioning treatment, as Carmubris is not authorised for this use, the company provided data from the medical literature.

What are the benefits and risks of Carmustine medac?

Because Carmustine medac is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's for its authorised indications.

For use as a conditioning treatment, data from the literature showed that Carmustine medac is effective at preparing patients with Hodgkin's lymphoma and non-Hodgkin's lymphomas for transplantation of their own haematopoietic progenitor cells. However, the data provided were not sufficient to demonstrate effectiveness in patients with other types of cancer and in those who are to receive cell transplant from a donor.

The side effects associated with Carmustine medac when used as a conditioning treatment are generally in line with those seen with the other uses.

Why is Carmustine medac authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Carmustine medac has been shown to be comparable to Carmubris. Therefore, the Agency's view was that, as for Carmubris, the benefit of Carmustine medac in the treatment of cancer outweighs the identified risk and it can be authorised for use in the EU.

For use a conditioning treatment, for which Carmubris is not authorised, the Agency noted that the active substance in Carmustine medac has been used for decades as a part of different conditioning regimens, and that its effectiveness has been established. Its safety profile in this use is similar to that seen with other uses. Therefore, the Agency decided that the benefits of Carmustine medac outweigh its risks as a conditioning treatment in patients with Hodgkin's lymphoma and non-Hodgkin's lymphomas before transplantation of their own haematopoietic progenitor cells.

What measures are being taken to ensure the safe and effective use of Carmustine medac?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Carmustine medac have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Carmustine medac are continuously monitored. Side effects reported with Carmustine medac are carefully evaluated and any necessary action taken to protect patients.

Other information about Carmustine medac

Carmustine Obvius received a marketing authorisation valid throughout the EU on 18 July 2018. The name of the medicine was changed to Carmustine medac on 13 September 2023.

Further information on Carmustine medac can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/carmustine-medac.

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