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# Phelinun (*melphalan*)

An overview of Phelinun and why it is authorised in the EU

## What is Phelinun and what is it used for?

Phelinun is a cancer medicine for treating patients with:

- cancers of the bone marrow (which produces blood cells) – multiple myeloma, acute lymphoblastic leukaemia and acute myeloid leukaemia;
- Hodgkin and non-Hodgkin lymphomas, which are cancers that affect white blood cells called lymphocytes;
- Childhood neuroblastoma, a cancer of nerve cells in different parts of the body;
- ovarian cancer;
- mammary adenocarcinoma, a type of breast cancer.

It is used either on its own or in combination with other cancer medicines, or radiotherapy or both.

Phelinun can also be used for stem cell transplantation in adults and children with blood cancers and some other blood disorders in children. It is given with other cytotoxic (cell-killing) medicines for conditioning treatment (to clear cells in the bone marrow) before the patient receives healthy stem cells from a donor to replace the diseased cells.

Phelinun contains the active substance melphalan.

Phelinun is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but Phelinun is intended for an additional use (conditioning treatment). The reference medicine for Phelinun is Alkeran 50 mg/10 ml, which is marketed in France.

## How is Phelinun used?

Phelinun can only be obtained with a prescription and it must be given under the supervision of a doctor experienced in the use of cancer medicines and conditioning treatment for stem cell transplantation.

Phelinun is given by infusion (drip) into a vein and the dose depends on the condition it is being used for as well as the patient's weight and height. The dose can be split and given over 2 or 3 consecutive days.

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**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 An agency of the European Union

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

## How does Phelinun work?

Melphalan, the active substance in Phelinun is a type of cytotoxic medicine known as alkylating agent. It prevents cells from dividing by stopping the DNA (the cell's genetic material) from duplicating itself to form new cells. Melphalan's action therefore affects cells that divide rapidly, such as cancer cells and cells of the bone marrow.

## What benefits of Phelinun have been shown in studies?

Studies on the benefits and risks of the active substance, melphalan, for the treatment of cancers have already been carried out with the reference medicine, Alkeran, and do not need to be repeated for Phelinun.

The company also provided evidence from over 20 published studies to show that melphalan is effective for conditioning treatment in adults and children undergoing haematopoietic (blood) stem cell transplantation.

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

## What are the risks associated with Phelinun?

The most common side effects with Phelinun (which may affect more than 1 in 10 people) include reduced levels of blood cells and platelets (blood components involved in clotting), infections, gastrointestinal disorders (such as diarrhoea, vomiting, mouth ulcers and bleeding) and disorders of the immune system (the body's natural defences) including graft-versus-host disease (transplanted cells attacking the body).

Phelinun must not be used during breast-feeding or as conditioning treatment during pregnancy.

For the full list of side effects and restrictions of Phelinun, see the package leaflet.

## Why is Phelinun authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Phelinun has been shown to be comparable to Alkeran for the treatment of blood cancers. Although main studies to measure the effectiveness of Phelinun for conditioning treatment in adults and children are not available, evidence from published studies shows that it is effective, and in some cases its side effects may be lower than those of other options for conditioning treatment.

The European Medicines Agency therefore decided that Phelinun's benefits are greater than its risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Phelinun?

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

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

## Other information about Phelinun

Phelinun received a marketing authorisation valid throughout the EU on 16 November 2020.

Further information on Phelinun can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/phelinun.

This overview was last updated in 11-2020.