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Mozobil (*plerixafor*)

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

What is Mozobil and what is it used for?

Mozobil is a medicine used to mobilise blood stem cells from a patient's bone marrow so that they can be collected and used later for transplantation in the same patient.

Mozobil is used together with the hormone granulocyte-colony stimulating factor (G-CSF) and is only for patients in whom collection of stem cells is difficult.

The patients who are given Mozobil are:

- adults with lymphoma or multiple myeloma (types of blood cancer);
- children from 1 year of age who have lymphoma or solid tumours.

Mozobil contains the active substance plerixafor.

The number of patients that need mobilisation and collection of haematopoietic stem cells for transplantation is low and Mozobil was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 October 2004. Further information on the orphan designation can be found on here: ema.europa.eu/medicines/human/orphan-designations/eu304227.

How is Mozobil used?

Mozobil is given as an injection under the skin. The medicine can only be obtained with a prescription and treatment should only be started and supervised by a doctor who has experience in treating cancer or blood disorders. After the patient has been given Mozobil, the patient's stem cells are extracted from the blood and stored before transplantation. Because of this, treatment should be carried out in collaboration with a specialised centre that has experience with this type of procedure and can monitor the stem cells.

Mozobil is used together with G-CSF. G-CSF is used on its own for 4 days before Mozobil is added. Mozobil is given 6 to 11 hours before the patient's blood is taken and the stem cells are extracted. It can be used for up to 7 consecutive days. The dose depends on the bodyweight of the patient.

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

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How does Mozobil work?

Mozobil is used to mobilise the stem cells from the bone marrow so they can be released into the blood. The active substance in Mozobil, plerixafor, works by blocking the activity of a protein called the 'CXCR4 chemokine receptor'. This protein normally helps to keep stem cells within the bone marrow. By blocking its activity, Mozobil allows the stem cells to be released into the blood, so that they can be collected.

What benefits of Mozobil have been shown in studies?

In two main studies involving 298 adults with non-Hodgkin's lymphoma and 302 adults with multiple myeloma, more patients who received Mozobil achieved the target number of stem cells and had successful engraftment of stem cells (the cells started growing and producing normal blood cells after transplantation) than patients who received placebo (a dummy treatment). In both studies the patients were also receiving G-CSF.

Among the adults with lymphoma, 59% (89 out of 150) of those receiving Mozobil achieved the target number of stem cells within 4 collection days, compared with 20% (29 out of 148) of the patients receiving placebo. Among the adults with multiple myeloma, 72% (106 out of 148) of those receiving Mozobil achieved the target number of stem cells within 4 collection days, compared with 34% (53 out of 154) of the patients receiving placebo.

In a main study involving 45 children with lymphoma or solid tumours, 80% (24 out of 30) of patients who received Mozobil had at least a doubling of the number of stem cells in the blood, compared with 29% (4 out of 14) patients who received standard mobilisation treatment alone.

What are the risks associated with Mozobil?

The most common side effects with Mozobil (which may affect more than 1 patient in 10) are diarrhoea, nausea (feeling sick) and reactions at the site of injection. For the full list of side effects and restrictions with Mozobil, see the package leaflet.

Why is Mozobil authorised in the EU?

The European Medicines Agency decided that Mozobil'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 Mozobil?

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

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

Other information about Mozobil

Mozobil received a marketing authorisation valid throughout the EU on 31 July 2009.

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

This overview was last updated in 05-2019.