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Plerixafor Accord (*plerixafor*)

An overview of Plerixafor Accord and why it is authorised in the EU

What is Plerixafor Accord and what is it used for?

Plerixafor Accord 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.

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

The patients who are given Plerixafor Accord are:

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

Plerixafor Accord is a 'generic medicine'. This means that Plerixafor Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Plerixafor Accord is Mozobil. For more information on generic medicines, see the question-and-answer document here.

Plerixafor Accord contains the active substance plerixafor.

How is Plerixafor Accord used?

Plerixafor Accord is given as an injection under the skin. It 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 Plerixafor Accord, their 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.

Plerixafor Accord is used together with G-CSF. G-CSF is used on its own for 4 days before Plerixafor Accord is started. Plerixafor Accord 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 Plerixafor Accord, see the package leaflet or contact your doctor or pharmacist.

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How does Plerixafor Accord work?

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

How has Plerixafor Accord been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Mozobil, and do not need to be repeated for Plerixafor Accord.

As for every medicine, the company provided studies on the quality of Plerixafor Accord. There was no need for 'bioequivalence' studies to investigate whether Plerixafor Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Plerixafor Accord is very similar to the reference medicine and when given by injection under the skin, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Plerixafor Accord?

Because Plerixafor Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Plerixafor Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Plerixafor Accord has been shown to be comparable to Mozobil. Therefore, the Agency's view was that, as for Mozobil, the benefits of Plerixafor Accord outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Plerixafor Accord?

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

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

Other information about Plerixafor Accord

Plerixafor Accord received a marketing authorisation valid throughout the EU on 16 December 2022.

Further information on Plerixafor Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/plerixafor-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 12-2022.