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Udenyca (*pegfilgrastim*)

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

What is Udenyca and what is it used for?

Udenyca is a medicine used in cancer patients to help with neutropenia (low levels of neutrophils, a type of white blood cell), which is a common side effect of cancer treatment and can leave patients vulnerable to infections.

It is given specifically to reduce the duration of neutropenia and prevent febrile neutropenia (when neutropenia is accompanied by fever).

Udenyca is not intended for use in patients with the blood cancer chronic myeloid leukaemia or with myelodysplastic syndromes (conditions in large numbers of abnormal blood cells are produced, which can develop into leukaemia).

Udenyca is a 'biosimilar medicine'. This means that Udenyca is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Udenyca is Neulasta. For more information on biosimilar medicines, see [here](#).

How is Udenyca used?

Udenyca can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of cancer or blood disorders. It is available as a prefilled syringe containing a solution for injection under the skin. Udenyca is given as a single dose of 6 mg injected under the skin at least 24 hours after the end of each cycle of chemotherapy (treatment with cancer medicines). Patients can inject themselves if they have been trained appropriately.

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

How does Udenyca work?

The active substance in Udenyca, pegfilgrastim, consists of filgrastim, which is very similar to a human protein called granulocyte-colony-stimulating factor (G-CSF). Filgrastim works by encouraging the

bone marrow to produce more white blood cells, increasing white blood cell counts and so treating neutropenia.

Filgrastim has been available in other medicines in the European Union (EU) for a number of years. In Udenyca, filgrastim has been 'pegylated' (attached to a chemical called polyethylene glycol). This slows down the removal of filgrastim from the body, allowing the medicine to be given less often.

What benefits of Udenyca have been shown in studies?

Laboratory studies comparing Udenyca with Neulasta have shown that the active substance in Udenyca is highly similar to that in Neulasta in terms of structure, purity and biological activity. Studies have also shown that giving Udenyca produces similar levels of the active substance in the body to giving Neulasta.

Because Udenyca is a biosimilar medicine, the studies on effectiveness and safety of pegfilgrastim carried out with Neulasta do not all need to be repeated for Udenyca.

What are the risks associated with Udenyca?

The most common side effect with Udenyca (which may affect more than 1 in 10 people) is pain in the bones. Pain in muscles is also common. For the full list of side effects and restrictions with Udenyca, see the package leaflet.

Why is Udenyca authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Udenyca has a highly similar structure, purity and biological activity to Neulasta and is distributed in the body in the same way.

All these data were considered sufficient to conclude that Udenyca will behave in the same way as Neulasta in terms of effectiveness and safety in its approved uses. Therefore, the Agency's view was that, as for Neulasta, the benefit of Udenyca outweighs the identified risk and it can be authorised for use in the EU.

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

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

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

Other information about Udenyca

Udenyca received a marketing authorisation valid throughout the EU on 21 September 2018.

Further information on Udenyca can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](https://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports).

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