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Cavoley (*pegfilgrastim*)

A plain-language overview of Cavoley and why it is authorised in the EU

What is Cavoley and what is it used for?

Cavoley is a medicine used in adults with cancer 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. Cavoley is given to reduce the duration of neutropenia and prevent febrile neutropenia (neutropenia accompanied by fever).

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

Cavoley contains the active substance pegfilgrastim and is a biological medicine. It is a biosimilar medicine; this means that Cavoley is highly similar to another biological medicine (the reference medicine) that is already authorised in the EU. The reference medicine for Cavoley is Neulasta. For more information on biosimilar medicines, see here.

How is Cavoley used?

Cavoley 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.

The medicine is given as an injection under the skin of the thigh, abdomen, belly or upper arm using a pre-filled syringe. One injection is given at least 24 hours after each cycle of chemotherapy. Patients may inject the medicine themselves if they have been trained appropriately.

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

How does Cavoley work?

The active substance in Cavoley, pegfilgrastim, is a form 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. In Cavoley, filgrastim has been pegylated (attached to a chemical called polyethylene

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glycol). This slows down the removal of filgrastim from the body, allowing the medicine to be given less often.

What benefits of Cavoley have been shown in studies?

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

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

Studies carried out with Cavoley are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Cavoley?

The safety of Cavoley has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of Neulasta

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

The most common side effect with Cavoley (which may affect more than 1 in 10 people) is pain in the bones. Muscle pain (which may affect up to 1 in 10 people) is also common.

Why is Cavoley authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Cavoley 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 Cavoley will have the same effects as Neulasta in its authorised uses.

Therefore, the Agency's view was that, as for Neulasta, the benefits of Cavoley 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 Cavoley?

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

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

Other information about Cavoley

Cavoley received a marketing authorisation valid throughout the EU on 25 September 2026.

Further information on Cavoley, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/cavoley.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 10-2026.