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Imreplys (*sargramostim*)

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

What is Imreplys and what is it used for?

Imreplys is a medicine used to treat people of all ages who have been exposed to high levels of radiation over a short period, resulting in bone marrow damage and development of haematopoietic sub-syndrome of acute radiation (H-ARS). Patients with H-ARS cannot produce enough new blood cells. This results in:

- low white blood cell counts, increasing the risk of infections;
- low red blood cell counts, leading to anaemia;
- low platelet (components that help the blood to clot) counts, which increases the risk of bleeding.

The medicine should be used in accordance with official radiological or nuclear emergency recommendations.

Imreplys contains the active substance sargramostim.

How is Imreplys used?

Imreplys can only be obtained with a prescription. Treatment should start as soon as possible after exposure to high doses of radiation, if the individual shows signs of H-ARS or if laboratory tests confirm it.

Imreplys should be given once daily as an injection under the skin of the belly, thigh or upper arm. In case of severe side effects, the doctor may have to reduce the dose or interrupt treatment. Patient's blood cell levels need to be regularly monitored. Treatment should continue until blood tests show that neutrophil (a type of white blood cell that fights infection) levels have stayed above a minimum level for 3 days in a row. Patients and caregivers may inject Imreplys themselves after they have been trained to do so.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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

How does Imreplys work?

The active substance in Imreplys, sargramostim, is very similar to a protein called granulocyte-macrophage colony stimulating factor (GM-CSF). It works the same way as natural GM-CSF in the body by encouraging the bone marrow to produce more white blood cells, including neutrophils, red blood cells as well as platelets. By increasing their levels, sargramostim helps restore the immune system and reduce the risks of infection and bleeding in people affected by H-ARS.

What benefits of Imreplys have been shown in studies?

Exposing people to radiation is not ethical and studies after accidental or deliberate exposure to high doses of radiation are not feasible. Therefore studies to assess the effectiveness of Imreplys in humans could not be carried out. The effectiveness of Imreplys was therefore evaluated based on 3 studies in over 500 monkeys exposed to radiation. When Imreplys was started within 2 days after they were exposed to radiation, the rate of death in monkeys given Imreplys was reduced by between 18 to 36 percentage points compared with those given placebo (a dummy treatment). The studies also showed that the monkeys given Imreplys had increased neutrophil and platelet levels, along with a reduction in infections.

The safety of Imreplys was assessed in studies involving humans (adults and children). In these studies, Imreplys was given to healthy individuals as well as people who had received body irradiation as a treatment for cancer.

What are the risks associated with Imreplys?

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

The most common side effects with Imreplys (which may affect more than 1 in 10 people) when given into a vein to patients with blood cancer include fever without infection, diarrhoea, vomiting, skin reactions, rash, weakness, metabolic laboratory abnormalities (abnormal blood or urine test values), malaise (feeling generally unwell), high glucose (blood sugar) levels, abdominal (belly) pain, weight loss, low albumin (a blood protein) levels, pruritis (itching), gastrointestinal haemorrhage (bleeding in the stomach and gut), chills, pharyngitis (sore throat), bone pain, chest pain, hypomagnesaemia (low magnesium levels), haematemesis (vomiting blood), arthralgia (joint pain), anxiety and eye haemorrhage (bleeding).

Some side effects can be serious. The most frequent include serious hypersensitivity (allergic) reactions including anaphylaxis, haemodynamic oedema (fluid retention), effusions (abnormal collections of fluid in hollow spaces or between tissues of the body) and fluid overload, and supraventricular arrhythmias (a type of abnormal or irregular heartbeat).

Why is Imreplys authorised in the EU?

At the time of authorisation, there were no treatments authorised for H-ARS, which is a life-threatening condition. The European Medicines Agency therefore identified a high unmet medical need.

The Agency considered that Imreplys is effective at treating H-ARS, based on studies in monkeys. The safety of the medicine was evaluated in patients with haematological (blood) conditions treated with total body irradiation. This was considered acceptable as it is expected that its safety will be similar in people with H-ARS. The side effects were predominantly mild to moderate in severity and consistent with the established safety profile of other approved medicines in the same class.

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

Imreplys has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about Imreplys for ethical reasons. The company must provide further data on Imreplys. It must submit a study about the effectiveness and safety of Imreplys in case the medicine is used in people exposed to high doses of radiation as well as yearly updates on any new information concerning the safety and efficacy of sargramostim. Every year, the Agency will review any new information that becomes available.

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

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

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

Other information about Imreplys

Imreplys received a marketing authorisation under exceptional circumstances valid throughout the EU on 21 August 2025.

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

This overview was last updated in 08-2025.