EMA/82143/2025
EMEA/H/C/006330

Vyjuvek (*beremagene geperpavec*)

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

What is Vyjuvek and what is it used for?

Vyjuvek is a medicine used to treat wounds in patients with dystrophic epidermolysis bullosa. Dystrophic epidermolysis bullosa is an inherited disease of the skin that makes the skin very fragile and causes severe blistering and scarring. Vyjuvek is intended for patients with dystrophic epidermolysis bullosa who have mutations affecting the *COL7A1 (*collagen type VII alpha 1 chain) gene.

Dystrophic epidermolysis bullosa is rare, and Vyjuvek was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 April 2018. Further information on the orphan designation can be found on the EMA website.

Vyjuvek contains the active substance beremagene geperpavec.

How is Vyjuvek used?

Vyjuvek can only be obtained with a prescription and should be started by a healthcare professional experienced in the management of patients with dystrophic epidermolysis bullosa.

Vyjuvek is available as a gel that is applied to wounds once a week. It might not be possible to start treatment of all wounds at the same time due to a maximum weekly recommended dose of the medicine. Vyjuvek should be applied to wounds until they are closed; it should not be used if no wounds are present.

A healthcare professional should apply Vyjuvek. Patients or caregivers may also apply Vyjuvek after training, if the healthcare professional considers it appropriate.

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

How does Vyjuvek work?

Patients with dystrophic epidermolysis bullosa have a mutation (change) in the *COL7A1* gene. This mutation means their skin cells are not able to make a working form of a protein called type VII

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

collagen (COL7), which helps to keep the layers of the skin together. The active substance in Vyjuvek is beremagene geperpavec, which consists of a virus (herpes simplex 1) that has been modified to contain the *COL7A1* gene. When Vyjuvek is applied to the wounds, the *COL7A1* gene is delivered into the skin cells, enabling them to produce the COL7 protein. This protein helps the layers of the skin to hold together, thereby promoting wound healing.

The virus used in this medicine cannot replicate or cause disease in humans.

What benefits of Vyjuvek have been shown in studies?

A main study involving 31 patients aged 1 to 44 years with dystrophic epidermolysis bullosa found that Vyjuvek was effective at healing wounds. Each patient received treatment for two wounds: one wound was treated with Vyjuvek and the other with placebo (a dummy treatment). At 6 months, 67% (21 out of 31) of the wounds treated with Vyjuvek were completely healed, compared with 22% (7 out of 31) of those treated with placebo.

What are the risks associated with Vyjuvek?

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

The most common side effects with Vyjuvek (which may affect up to 1 in 10 people) include chills and pruritus (itching).

Why is Vyjuvek authorised in the EU?

There is an unmet clinical need in the treatment of dystrophic epidermolysis bullosa, and persistent skin lesions caused by the disease represent a great physical, emotional and psychological burden for patients. Vyjuvek was shown to be effective at healing wounds and has a manageable safety profile.

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

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

The company that markets Vyjuvek must provide results from a study on the long-term safety of Vyjuvek in patients with dystrophic epidermolysis bullosa with mutations in the *COL7A1* gene, including in patients younger than 6 months of age.

The company will also provide educational materials for healthcare professionals on how to properly store, prepare and apply Vyjuvek. Patients and caregivers will also receive educational materials on the use of Vyjuvek.

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

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

Other information about Vyjuvek

Vyjuvek received a marketing authorisation valid throughout the EU on 23 April 2025

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

This overview was last updated in 04-2025.