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EPAR summary for the public

Regranex

becaplermin

This document is a summary of the European Public Assessment Report (EPAR) for Regranex. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Regranex.

What is Regranex?

Regranex is a gel that contains the active substance becaplermin.

What is Regranex used for?

Regranex is used together with other wound care measures to help granulation (healing) of long-term skin ulcers in people with diabetes. Regranex is used on neuropathic ulcers up to 5 cm^2 in size. Neuropathic ulcers are caused by a nerve problem, and not by a problem with the blood supply to the area affected.

The medicine can only be obtained with a prescription.

How is Regranex used?

Treatment with Regranex should be started and monitored by a doctor who has experience in the management of diabetic wounds.

The ulcer should be cleaned with water or saline (salt) solution before each application of Regranex. The gel should then be applied as a layer to the entire surface of the ulcers once a day using a clean application aid, such as a cotton swab. The sites should then be covered by a moist saline gauze dressing to keep the area moist while the ulcers are healing. The dressing should not be air- or watertight.

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Regranex should not be used for more than 20 weeks, and should always be used alongside other measures that help ulcers heal, such as keeping them clean and not applying any pressure onto them while they are healing. Each tube of Regranex should only be used on one patient. Regranex should be used carefully to make sure that the gel does not become contaminated with bacteria. See the Package Leaflet for further details.

How does Regranex work?

The active substance in Regranex, becaplermin, is a copy of a human protein called platelet-derived growth factor-BB. Growth factors are proteins that stimulate cells to multiply. Platelet-derived growth factors act on cells that are involved in repairing wounds. Becaplermin is produced by a method known as 'recombinant DNA technology': it is made by a yeast that has received a gene (DNA), which makes it able to produce human platelet-derived growth factor-BB. Becaplermin acts in the same way as the naturally produced growth factor by stimulating cell growth and helping the growth of normal tissue for healing.

How has Regranex been studied?

Regranex has been studied in one main study and three additional studies involving diabetic adults who had had at least one diabetic ulcer for at least eight weeks. In total, there were 922 ulcers in the studies. Regranex was compared with placebo (a dummy treatment) and with no treatment, but all of the patients received standard wound care. The main measure of effectiveness was the number of ulcers that had completely healed after 20 weeks.

What benefit has Regranex shown during the studies?

When the results of all four studies were looked at together, Regranex healed about 10% more ulcers than the placebo gel. In the patients who used Regranex, 47% of the ulcers that were less than 5 cm^2 in size healed. This compared to 35% in the patients using the placebo gel and 30% in the patients who were given only standard wound care.

What is the risk associated with Regranex?

The most common side effects with Regranex (seen in more than 1 patient in 10) are infected skin ulcers and cellulitis (inflammation of the deep skin tissue). For the full list of side effects reported with Regranex, see the Package Leaflet.

Regranex should not be used in people who may be hypersensitive (allergic) to becaplermin or any of the other ingredients. It must not be used in people with any known cancer or who have ulcers that are infected.

Why has Regranex been approved?

The CHMP decided that Regranex's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Regranex:

The European Commission granted a marketing authorisation valid throughout the European Union for Regranex to Janssen-Cilag International NV on 29 March 1999. After 10 years, the marketing authorisation was renewed for a further five years.

The full EPAR for Regranex can be found here. For more information about treatment with Regranex, read the Package Leaflet (also part of the EPAR).

This summary was last updated in 04-2010.