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Questions and answers on the cessation of supply of Regranex (becaplermin)

The European Medicines Agency has been notified by Janssen-Cilag International NV of its intention to end the supply of Regranex in Europe from 30 June 2011 onwards. The company states that this decision has been made for commercial reasons. Healthcare professionals will receive a letter from the company informing them of the cessation of supply.

What is Regranex?

Regranex is a gel that contains the active substance becaplermin. It is used together with other wound care measures to help the healing of long-term neuropathic skin ulcers (ulcers caused by a nerve problem) in people with diabetes.

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. Becaplermin works in the same way as the naturally produced growth factor by stimulating cell growth and helping the growth of normal tissue for healing.

Regranex has been authorised in the European Union (EU) since 29 March 1999 and is marketed in seven Member States¹.

Why is the supply of Regranex ending?

The company that makes Regranex, Janssen-Cilag International NV, has informed the Agency that it will permanently end the supply of Regranex from 30 June 2011. The company stated that this decision has been made as a consequence of very low demand and since alternative management options for skin ulcers in diabetes are available.

¹ Regranex is marketed in Austria, France, Germany, Ireland, the Netherlands, Spain and the United Kingdom.

What will happen next?

The company will provide a letter to healthcare professionals, informing them of the planned end of supply. Although the company is discontinuing Regranex, it will complete an ongoing epidemiological study to evaluate any possible risk of cancer with Regranex.

The letter will also remind healthcare professionals who may prescribe Regranex until supplies run out about the appropriate use of the medicine, and that it should not be used in patients who have or have had cancer anywhere in the body.

What are the recommendations for patients and prescribers?

- Patients and healthcare professionals should note that from 30 June 2011 stocks of Regranex will start to run out.
- Doctors who are currently prescribing Regranex should start making plans to switch their patients to alternative options.
- Until supplies run out, doctors may prescribe Regranex according to the latest product information and are reminded that Regranex should not be used in patients who have or have had cancer anywhere in the body.
- Patients using Regranex should discuss with their doctor alternative management options for diabetic ulcers. Patients who have any questions should speak to their doctor or pharmacist.