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Press Office

Press release

European Medicines Agency recommends contraindication for Regranex in patients with any pre-existing cancer

Following a review of the available data on a possible risk of cancer in patients using Regranex (becaplermin), from Janssen-Cilag International N.V., the European Medicines Agency has concluded that the medicine must not be used in patients who have any form of cancer. A similar restriction previously applied, but only for patients who had a skin cancer close to the area where the gel was to be applied.

Regranex is a gel that is used together with other wound care measures to treat long-term skin ulcers in people with diabetes.

Patients using Regranex who have or have had cancer should speak to their doctor at their next routine appointment in order to arrange alternative treatment.

The review, conducted by the Agency's Committee for Medicinal Products for Human Use (CHMP), was initiated at the request of the European Commission because of reports of cancer developing in a small number of patients using the gel. In an observational study, that compared Regranex-users with a control group of patients who did not use Regranex, the overall risk of developing cancer was not found to be significantly different between Regranex-users and non-users. However, patients who used three or more tubes of Regranex and who developed cancer had a greater risk to die of their cancer than patients who did not use Regranex. The study had several limitations in its design, including a small number of cases of cancer and is therefore not considered to be robust.

The Committee noted that while there was no firm evidence of a link between Regranex and cancer there was also not enough evidence to rule out such a link. Therefore, the CHMP concluded that, as a precautionary measure, the gel must not be used in patients with a pre-existing cancer.

The Committee also asked the company to provide more information on the possible absorption of the medicine into the body, and to perform another epidemiological study to generate more robust evidence on the possible link of Regranex with cancer and cancer outcomes.

The CHMP's recommendation has now been forwarded to the European Commission for the adoption of a legally binding decision.

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Notes

1. A question-and-answer document with more information is available here.
2. The CHMP reviewed the marketing authorisation of Regranex on the request of the European Commission under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated in cases where there are public health concerns with a centrally authorised medicine.
3. Regranex was first authorised in March 1999. It is currently available in Austria, France, Germany, Ireland, the Netherlands, Spain and the United Kingdom.
4. More information is available in the European Public Assessment Report (EPAR) at http://www.emea.europa.eu/humandocs/Humans/EPAR/regranex/regranex.htm
5. This press release, together with other information on the work of the Agency, can be found on the Agency's website: www.emea.europa.euThis press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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