

9th June 2011

Regranex®Gel (becaplermin 0.01%) - Cessation of Supply in Europe

Dear Healthcare Professional,

This letter is sent to inform you that the supply of Regranex® Gel (becaplermin 0.01%) in Europe will permanently end from 30th June 2011. This decision has been made for commercial reasons as a consequence of very low demand and the availability of alternative therapeutic options.

Although the product is discontinued, an ongoing epidemiological study to evaluate whether any exposure to becaplermin increases risk of incident cancer and/or cancer death will be completed and be submitted to European Regulatory Authorities in February 2012.

Prescribers are reminded that Regranex® Gel is contraindicated in patients with any known malignancies in recognition that the product promotes cellular proliferation and angiogenesis. Please refer to the product information (SPC) regarding the safe and appropriate use of Regranex, for patients still using the product. In particular, prescribers should re-evaluate the need for treatment after 10 weeks if no meaningful healing progress is evident, and Regranex should be withdrawn if an infection occurs during treatment. No specific recommendations are required to stop treatment with Regranex® Gel.

Call for reporting

Please continue to report any suspected adverse drug reactions which should be reported to the Irish Medicines Board via the on-line reporting system at www.imb.ie

Suspected adverse drug reactions should also be reported to Janssen on +44 1494 567447

If you require further information, please contact Janssen Medical Information on 1800 709 122

Yours faithfully,



Dr Michelle De Brún
Head of Medical Affairs, Ireland
Janssen
00353 16202308
00353 868511069
mdebrun@its.inj.com

Janssen-Cilag Ltd

Block B, Liffey Valley Office Park
Quarryvale, Co. Dublin, Ireland
tel (01) 620 2300 fax (01) 626 3592
www.janssen.ie

Registered Office

Janssen-Cilag Ltd 50-100 Holmers Farm Way
High Wycombe Buckinghamshire HP12 4EG UK
tel +44 (0) 1494 567567 fax +44 (0) 1494 567568
Registered in England 1027904