# Urgent Field Safety Notice

**NOVABEL®**

**FSCA: 23 July 2010**

**Advice by the manufacturer not to use Novabel® any more**

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23 July 2010

**Sender:**
Merz Pharmaceuticals GmbH
Eckenheimer Landstraße 100
60318 Frankfurt am Main
Germany

**Addressees:**
Physicians using Novabel®

**Details on affected devices:**
Novabel®, Dermal Filler, (1x1ml, Art.-Nr. 40800, all batches)
Novabel®, Dermal Filler, (2x1ml, Art.-Nr. 49021, all batches)

**Description of the problem including potential reasons:**
Merz Aesthetics has recently, proactively informed you of adverse reactions reported in a few patients treated with Novabel®. As of June 21, 2010, Merz Global Drug Safety Department has received an overall number of 70 case reports (from an estimated total number of 24,000 syringes sold) from post-marketing surveillance. This number includes short term transient adverse reactions such as redness, bruising, pain and swelling common with all fillers. Included in these reports are 26 patients presenting with nodules and 10 patients with indurations, mostly in the infra-orbital area. Many of these have resolved since being reported. Also included in these reports are 3 cases of histologically confirmed granuloma.

Although the overall assessment of the safety situation for Novabel® remains unchanged we ask you not to use Novabel® outside clinical investigations any more. This advice is given due to the fact that nodules are visible and palpable and represent a dissatisfactory aesthetic outcome in the concerned patients.

Merz would like to better understand the predictive factors for these reactions and intends to provide effective treatment protocols for such situations prior to supporting the utilization and commercial availability of Novabel®.

**Advise on action to be taken by the user:**
We ask you not to use Novabel® outside clinical investigations any more until we can provide the aforementioned treatment protocols.

Merz asks for your continued diligence in monitoring patients previously injected with Novabel®. Should you need any additional support or information please contact our Merz Medical Affairs Department (contact information below).

Our aim is to confidently promote Novabel® when we can provide patients and physicians reassurance there are effective treatment options.

For quality assurance and compliance purposes, please fax back the attached acknowledgement immediately upon receipt of this document.

**Transmission of this Field Safety Notice**:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
Please transfer this notice to other organizations on which this action has an impact.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact reference person:**

*Dr Andrew Makin*
*Medical Director*
*Merz Pharma UK Ltd*
*260 Centennial Park*
*Elstree Hill South*
*Elstree*
*Herts WD6 3SR.*
*Tel: +44 (0) 20 8236 0000 (Monday-Friday 09.00-17.00)*

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We thank you for your understanding and collaboration in this matter.

**Signature**

[redacted]
**Managing Director – Merz Pharma UK Ltd.**

**FAX BACK ACKNOWLEDGEMENT**

**I, _____ (printed name) acknowledge that I have received and understood this letter on _____ (printed date).**

**Signature; _____**

**Please fax this page to the following number: _____**

(*MPUK Secure Fax: 0333 200 4142*)