

# Medical Device Alert

## Immediate action

Ref: MDA/2010/064 Issued: 12 August 2010 at 12:00

### Device

Novabel<sup>®</sup> dermal filler.

Manufactured by Merz Pharmaceuticals GmbH.

1x1 ml, Art.-Nr. 40800 and 2x1ml, Art.-Nr. 49021.

All batches.

Problem	Action
<p>Use of Novabel<sup>®</sup> dermal filler may cause adverse reactions.</p>	<ul style="list-style-type: none"> <li>• Do not use Novabel<sup>®</sup> dermal filler.</li> <li>• Return all unused product to Merz Pharma UK Ltd.</li> <li>• Monitor patients who have received Novabel<sup>®</sup> and in particular those who exhibit symptoms linked to the use of Novabel<sup>®</sup>.</li> </ul>
<h3>Action by</h3> <p>Doctors, dermatologists, nurses, dentists and any professionals trained for administration of Novabel<sup>®</sup>. Plastic surgeons.</p>	
CAS deadlines	Contact
<p>Action underway: 16 August 2010 Action complete: 02 September 2010</p>	<p><b>Manufacturer</b> Medical Information Department Merz Pharma UK Ltd Tel: 020 8236 0000 Fax: 020 8236 3501 Email: <a href="mailto:medical.information@merz.com">medical.information@merz.com</a></p>

## Device

Novabel<sup>®</sup> is a colourless dermal filler composed of cross-linked alginate. It is supplied in a prefilled, 1 ml, single-use syringe with two sterile 30G ½ needles.

## Problem

Merz Pharmaceuticals GmbH issued a [Field Safety Notice](#) (dated 23 July 2010), advising practitioners to stop using Novabel<sup>®</sup>.

The manufacturer has received reports of adverse reactions to the filler including redness, bruising, pain, swelling and histologically confirmed granuloma. They have also received reports of nodules and indurations in the infra-orbital area.

## Action

- If you administer Novabel<sup>®</sup>:
  - cease use of the product
  - return unused syringes to Merz Pharma UK Ltd.
  - following application, patients should have been advised to return and seek treatment in case of progressive adverse reactions including redness, bruising, pain, swelling, nodules, indurations and granuloma
  - follow up patients who exhibit residual adverse symptoms (described above) three months after application
  - where symptoms persist, consider referring patients to a plastic surgeon for further treatment.
  
- If you are a plastic surgeon:
  - if a patient presents with symptoms linked to Novabel<sup>®</sup> use, consider the need to treat with minocycline or injectable steroids.

## Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

### Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

#### Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Day surgery units
- Dental departments
- Dental nurses
- Dentists
- General surgical units, directors of
- Health and safety managers
- Medical directors
- Nursing executive directors
- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of
- Outpatient clinics
- Outpatient theatre managers

- Outpatient theatre nurses
- Pharmacists
- Purchasing managers
- Supplies managers

**Care Quality Commission (CQC) (England only) to:**

The MHRA considers this information to be important to:

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

**Health Protection Agency to:**

Directors for onward distribution to:

- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- Risk manager
- Safety officers

**Primary care trusts to:**

CAS liaison officers for onward distribution to all relevant staff including:

- Community dental practices
- Community hospitals
- Community nurses
- Community pharmacists
- Directors of public health
- General dental practitioners
- General practitioners
- NHS walk-in centres
- Practice nurses

## Contacts

**Manufacturer**

Medical Information Department  
Merz Pharma UK Ltd  
260 Centennial Park  
Elstree Hill South  
Elstree  
Herts WD6 3SR

Tel: 020 8236 0000

Fax: 020 8236 3501

Email: [medical.information@merz.com](mailto:medical.information@merz.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/064** or **2010/007/023/081/016**.

**Technical aspects**

Miss Feza Haque or Mr Ian Smith  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3066 / 3306

Fax: 020 7084 3106

Email: [feza.haque@mhra.gsi.gov.uk](mailto:feza.haque@mhra.gsi.gov.uk)  
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**Clinical aspects**

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**How to report adverse incidents**

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

**Northern Ireland**

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald BT4 3SQ  
Tel: 02890 523 704  
Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

**How to report adverse incidents in Northern Ireland**

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>  
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

**Scotland**

Enquiries and adverse incident reports in Scotland should be addressed to:  
Incident Reporting and Investigation Centre  
Health Facilities Scotland  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh EH12 9EB  
Tel: 0131 275 7575  
Fax: 0131 314 0722  
Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)  
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes  
Senior Medical Officer  
Medical Device Alerts  
Welsh Assembly Government  
Cathays Park  
Cardiff CF10 3NQ  
Tel: 029 2082 3922  
Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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