Medical Device Alert

Immediate action

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

Device

Novabel® dermal filler.
Manufactured by Merz Pharmaceuticals GmbH.
1x1 ml, Art.-Nr. 40800 and 2x1ml, Art.-Nr. 49021.
All batches.

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| Use of Novabel® dermal filler may cause adverse reactions. | • Do not use Novabel® dermal filler.  
• Return all unused product to Merz Pharma UK Ltd.  
• Monitor patients who have received Novabel® and in particular those who exhibit symptoms linked to the use of Novabel®. |

Action by

Doctors, dermatologists, nurses, dentists and any professionals trained for administration of Novabel®.  
Plastic surgeons.

CAS deadlines

Action underway: 16 August 2010  
Action complete: 02 September 2010

Contact

**Manufacturer**  
Medical Information Department  
Merz Pharma UK Ltd  
Tel: 020 8236 0000  
Fax: 020 8236 3501  
Email: medical.information@merz.com
Device

Novabel® 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®.

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®:
  - 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® 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

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
ian.smith@mhra.gsi.gov.uk
Clinical aspects
Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 020 7084 3126
Fax: 020 7084 3111
Email: nicola.lennard@mhra.gsi.gov.uk

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
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.iric@nhs.net
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