Medical Device Alert

Ref: MDA/2012/022 Issued: 25 April 2012 at 14:00

Device

Dermal filler for breast augmentation.

Macrolane™ Volume Restoration Factor (VRF).

Manufactured by Q-Med AB (a Galderma division).

Problem

Use of Macrolane VRF20 and Macrolane VRF30 for breast augmentation can make diagnosis of breast cancer more difficult, particularly with the use of mammography.

Action by

Breast surgeons
Cosmetic surgeons
GPs
Mammographers
Plastic surgeons
Radiographers
Radiologists

Action

Do not use Macrolane for breast augmentation.

Have procedures in place for radiographers to check with patients presenting for breast examination for any history of breast injection. Staff should request the card (appendix 1) that the patient was given at the time of injection, identifying Macrolane as the product used, and pass it on to the examining radiologist.

Women may present with concerns that the injected Macrolane has affected mammogram results. GPs may wish to consider referral for repeat imaging.

CAS deadlines

Action underway: 30 April 2012

Action complete: 14 May 2012

Contact

Manufacturer
David Wall
Galderma UK & Ireland
Tel: 01923 208 950
Fax: 01923 208 998
Email: David.wall@galderma.com

Device

Macrolane VRF20 and VRF30 is an injectable filler for volume restoration and body contouring in a range of indications including breast augmentation.

Problem

The MHRA has been made aware of a Dear Doctor Letter issued in April 2012 (appendix 2) to clinicians by Q-Med about the use of Macrolane recommending that it is not used for injection into breasts because it can make diagnosis of breast cancer more difficult, particularly during mammography.

The manufacturer has stated:

> ‘Macrolane is detectable in mammography, ultrasound examination and MRI examination of the breasts.
>
> **Mammograms**
> A clinical study indicates that the presence of Macrolane may significantly reduce the diagnostic quality of mammograms, since Macrolane will appear as a gray/white shadow in the mammogram. In this case ultrasound can be used as a complementary examination.
>
> **Ultrasound**
> Ultrasound can be used to diagnose lumps in the breast after a Macrolane treatment. Ultrasound may also be a complement to mammography at breast screening and diagnosing. Some radiologists explain that Macrolane has a typical appearance in an ultrasound, similar to that of water, but with a snowstorm appearance.’

(http://www.q-medpractitioner.com/International/Macrolane/Radiologists/)

There is no association with cancer and no safety concerns have been identified for this product. The product remains on the market for use elsewhere in the body. The manufacturer plans to issue updated instructions for use in due course with updated indications for Macrolane use.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- 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 relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

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

- Breast nurse specialists
- Breast screening units
- Breast surgeons
- Clinical governance leads
- General surgeons
- General surgery
- General surgical units, directors of
- Mammography units
- Medical directors
- Medical oncologists
- Medical oncology, directors of

- Nursing executive directors
- MRI units, directors of
- Outpatient clinics
- Plastic surgeons
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers

Primary care trusts

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

- Directors of public health
- General practitioners

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Clinics
- Cosmetic surgeons
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

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Fax: 01923 208 998

Email: David.wall@galderma.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/022** or **2012/004/023/291/010**

Technical aspects

Miss Feza Haque or Mr Ian Smith
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7066 / 7306
Fax: 020 8754 3965

Email: 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

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

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:
Dr Chris Jones
Medical Director
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

Appendix 1

INFORMATION FOR YOUR RADIOLOGIST

Ms/Mrs._____was treated with Macrolane™.

Macrolane VRF20 & VRF30 (manufactured by Q-Med AB, Uppsala, Sweden) is approved in the EU for breast enhancement, volume restoration and contouring of body surfaces.

Macrolane VRF20 & VRF30 are NASHA™ gels and as such consist of stabilized sodium hyaluronate (hyaluronic acid) of non- animal origin (20 mg/ml) and phosphate buffered saline at pH 7. Macrolane is biodegradable and it contains approximately 2% hyaluronic acid (w/w) and 98% (w/w) water. The rate of degradation of Macrolane varies between individuals and clinical studies show that the complete degradation process would take 12 to 24 months or longer.

Macrolane is an injectable viscoelastic gel. Such gels have been used for many years as fillers to treat wrinkles. As Macrolane is implanted by injection, both large coherent deposits and small deposits of gel can be present. Macrolane is usually injected below the mammary gland and above the pectoral muscle but in some patients the product is placed underneath the pectoral muscle in order to achieve good results.

Clinical studies show that Macrolane is detectable on mammography, ultrasound examination and MRI examination of the breasts. A recent clinical study indicates that the presence of Macrolane may affect the diagnostic quality of parts of the mammograms performed for breast cancer screening purposes. Ultrasound can be used if complementary examinations are needed. Pre-implant mammograms may also facilitate post-treatment mammography evaluations. The following figures illustrate the appearance of Macrolane on mammography, MRI and ultrasound.

For more information, please also see www.macrolane.com

Macrolane

FIRST TREATMENT

The following volume of Macrolane was injected:

	Volume in right breast	Volume in left breast
Under the mammary gland	ml	ml
Under the Pectoralis muscle	ml	ml

Date of treatment: _____

Mammography pre-treatment ☐ Yes ☐ No Ultrasound pre-treatment ☐ Yes ☐ No

_____

Treated by Doctor:

_____

Telephone number to Doctor:

RETREATMENT

The following volume of Macrolane was injected:

	Volume in right breast	Volume in left breast
Under the mammary gland	ml	ml
Under the Pectoralis muscle	ml	ml

Date of treatment: _____

Mammography pre-treatment ☐ Yes ☐ No Ultrasound pre-treatment ☐ Yes ☐ No

_____

Treated by Doctor:

_____

Telephone number to Doctor:

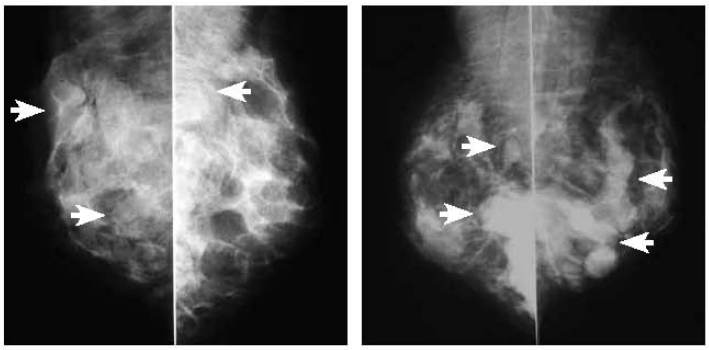

Figure 1. Twelve-month mammograms (MLO projection) from two, representative study participants. The arrows indicate the location of implanted HA gel.

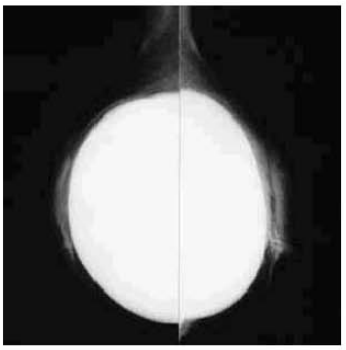

Figure 2. Mammograms (MLO projection) of breasts augmented with silicone – the opaque implants are clearly visible.

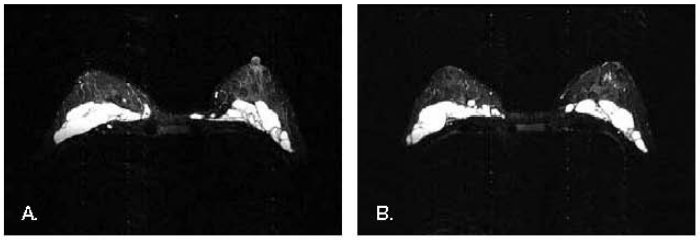

Figure 3. MRI scans performed at 3 months (A) and 12 months (B) following implantation of HA gel (both scans are transverse STIR sequences from the same patient).

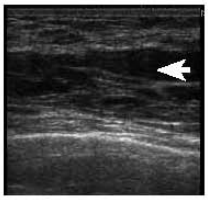

Figure 4. Ultrasound image 6 months after treatment. Pictures courtesy of Dr. Millefiori.

Appendix 2

Uppsala, Sweden
April 17, 2012

Q-Med, a Galderma division, provides update on the use of Macrolane for breast augmentation

Dear Doctor and valued Macrolane customer:

Macrolane is a safe and well-tolerated injectable product used to enhance body contour and correct soft tissue defects. Introduced in 2008, it has improved quality of life for thousands of patients across various indications ranging from HIV-related lipoatrophy to breast augmentation. A safety reporting system has been in place since launch and no safety concerns have been identified.

However, because of the ongoing and unresolved debate relating to radiology examination of breasts treated with injectable products, Q-Med has decided to discontinue Macrolane for breast augmentation until further notice.

No safety concerns have been identified with Macrolane

Because no safety concerns have been identified, women who have undergone breast augmentation with Macrolane do not need to take any actions other than to attend their follow-up consultations as scheduled after injection.

Breast augmentation and screening procedures

As with any breast prostheses, it is important that patients inform the healthcare professional conducting their breast examination of the date of their last Macrolane treatment prior to the assessment. The currently validated approach to conducting breast screening in women who have received Macrolane treatment is summarised on page 2 of this letter.

Furthermore, Q-Med continues to invest in research to confirm screening protocols for women who have received Macrolane for breast augmentation, as described on page 2 of this letter.

Macrolane remains available for use in other approved indications

Q-Med will continue to promote Macrolane for body contouring procedures and soft tissue defects. Q-Med is also pursuing a number of potential new uses for Macrolane-like gels.

Further information

Q-Med will follow up this letter with a personal contact to discuss any concerns that you may have with respect to the decision, your patients or your clinic. Q-Med will also make available a patient leaflet to address potential concerns from your patients who have received Macrolane. We will also update the Macrolane website (www.macrolane.com) with any further developments in this situation.

We wish to thank you for your support for Macrolane, and we look forward to our continued relationship.

Regards

[Signature]

Name

Position

1

Addressing the interference of breast augmentation with mammography

All breast augmentation procedures can interfere in the reading of mammograms. This is well-recognised and is typically addressed by using additional standard assessment techniques or radiology investigations. To use ultrasound as an adjunct to mammography is not unusual, particularly in women with dense breast for whom the sensitivity of screening mammography may be reduced.

Macrolane can interfere with reading of mammography. The current Macrolane product information provides very clear information about this. Q-Med supports international recommendations on the importance of baseline examination prior to breast augmentation. After breast enhancement, digital mammography is the preferred method of obtaining adequate information for screening purposes. Supplemental ultrasound may also be employed. This sequence of investigations has been proposed by expert radiologists.

Confirming best practices in breast screening for women treated with Macrolane

A 24-month follow-up study was recently conducted in Sweden and France to evaluate any potential difficulties with the interpretation of digital mammography image(s) or ultrasonography and the value of this combination of radiology investigations. The preliminary results of this study suggest that an adequate examination can be performed using those techniques. Q-Med will make the 24-month follow-up data available as soon as possible to facilitate optimal clinical follow-up of women treated with Macrolane.