



URGENT FIELD SAFETY NOTICE

AquaUltra Clear ultrasound transmission gel

IMPORTANT INFORMATION!

THIS FIELD SAFETY NOTICE HAS BEEN UPDATED SINCE THE PREVIOUS VERSION ISSUED ON
17 OCTOBER 2024

Ultragel Medical Kft is issuing an urgent Field Safety Notice to inform users about the potential risk of microbial contamination in Ultrasound Gel.

Further to publication of the FSN on 17.10.2024, it has come to light that there is potential risk of contamination in additional Lots, therefore the scope of the recall has been widened.

Commercial name of the affected product:

AQUAULTRA CLEAR ULTRASOUND GEL 260g

Ref: UC260pp

Distr Ref: M316-C

UDI: (01)05060816220295

Primary clinical purpose of device:

Topical skin coupling gel for use in non-invasive ultrasound scanning procedures.

Instructions for Use included with the product:

- External use only
- Product is non sterile
- Do not apply the gel on skin affected by abrasions, erythema or wounds
- Close the bottle after use
- May cause irritation or redness with allergic persons
- Contact with eyes may cause irritation
- Analyst with sensitive skin should wear protective gloves during use
- Do not use the gel after the "use by" date on the bottle
- Product should be used within 3 months of opening.

Type of action:

To withhold distribution and recall affected product **Lots** from the market.

Date:

7 November 2024

Attention:

Patients, Healthcare Professionals, Distributors


Ultragel Medical Kft.

✉ 1022 Budapest, Aranka utca 12.
☎ +36 1 278 3057

✉ info@ultragelmedical.hu
🌐 www.ultragelmedical.hu

FSN re M316-C AquaUltra Clear
v02 revised 7.11.2024

Details of affected product:

Brand Name	Lot No	Expiry Date	Photograph
Ebrington Medical AquaUltra clear ultrasound gel 260g	2024.04 <u>2024.06</u>	2027.04 <u>2027.06</u>	

Description of problem:

There is a potential risk of microbial contamination (*Burkholderia stabilis*) in the affected **Lots** of ultrasound gel. This potential link with ultrasound gel was identified during an investigation by public health authorities and the investigation is ongoing. The affected Lots were distributed during **May to October 2024**.

Predicted risk to patients/users:

There is a potential risk of developing infection caused by *Burkholderia stabilis* if the affected ultrasound gel is used. The risk is higher in patients with cystic fibrosis, severe lung disease, severe immunocompromised and intensive care patients.

Advice on action to be taken by users/healthcare professionals:

- Stop using products from affected **Lots** immediately.
- Quarantine and dispose of the affected product.
- Complete attached acknowledgement form giving confirmation of product quantities disposed of.
- Healthcare professionals who are contacted for advice should consider appropriate review of patient's health.



Advice on action to be taken by distributors/supply chain:

- Stop supplying the affected **Lots** immediately.
- Quarantine all remaining stock of the affected **Lots 2024.04 and 2024.06.**
- Advise UK Distributor (contact details below) of remaining stock levels of affected **Lots.**
- Liaise with UK Distributor regarding disposal of affected **Lots.**

UK Distributor:

- Ebrington Medical
1a Carrakeel Drive, Maydown BT47 6UQ
Telephone: 028 7134 5188
Email: info@ebrington-ni.com

Transmission of this Field Safety Notice:

This notice needs to be passed to all those who need to be aware of the potentially affected product.

Contact for further information:

- Ultragel Medical Kft
Aranka utca 12
1022 Budapest
Hungary
Telephone: +36 1 278 3057
Email: info@ultragelmedical.hu

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CONFIRMATION OF DISPOSAL OF STOCK

Field Safety Notice regarding **AquaUltra Clear Ultrasound Transmission Gel**,
Lot 2024.04 and Lot 2024.06

Company Name	
Address	
Quantity of product for disposal	
AquaUltra <u>Lot 2024.04</u>	
AquaUltra <u>Lot 2024.06</u>	
Signed	
Name	
Email address	
Contact number	

Please return this completed form to the UK Distributor:

Ebrington Medical
1a Carrakeel Drive
Maydown BT47 6UQ

Telephone: 028 7134 5188

Email: info@ebrington-ni.com