



# HPRA

An tÚdarás Rialála Táirgí Sláinte  
Health Products Regulatory Authority

# Safety Notice

## Medical Devices

### Juvéderm ULTRA 4

Priority 2 – Warning



HPRA Safety Notice: 2014(45)

Issue Date: 12 December 2014

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
N/A Counterfeit product- Chinese manufacturer. Supplier- unknown.	MS22683

#### ISSUE

Counterfeit Juvéderm ULTRA 4 dermal filler may be in circulation in Ireland and can be identified by the misspelled word REJUVENATION, which appears on the side of the box as ERJUVENATION, shown above.

#### ACTION OR RECOMMENDATIONS

The HPRA advises that users:

Do NOT use this counterfeit product on patients or clients;

- 1 Contact the HPRA (at the contact details below) immediately if you come across this counterfeit Juvéderm product.
- 2 Device packaging, labelling, instructions and product should always be checked before use to determine if anything looks unusual.

TARGET GROUPS	
Plastic surgery clinics Beauty salons	Medical aesthetic clinics

BACKGROUND
<p>We have been notified that a shipment of CE marked Juvéderm ULTRA 4 (hyaluronic acid injection) dermal filler has been seized in another country. The product contains the following error in labelling "Science of Erjuvenation". The correct label is "Science of Rejuvenation" based on the real manufacturer's, Allergan, artwork. The manufacturer, Allergan, has confirmed that the product pictured above is counterfeit.</p> <p>The safety, performance and quality of this counterfeit product is <b>not</b> assured.</p>

HPRA CONTACT INFORMATION	
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