HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Safety Notice

## Medical Devices

# Neutrogena Visibly Clear Light Therapy Acne Mask and Activator


**Priority 1 – For Immediate Action**

**HPRA Safety Notice: SN2019(27)** **Issue Date: 18th July 2019**

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|---|---|
| Johnson & Johnson (Ireland) Limited (Neutrogena) | V40485 |

| ISSUE |
|---|
| Johnson & Johnson (Ireland) Limited has become aware of a number of reports of visual effects associated with use of the Neutrogena® Visibly Clear Light Therapy Acne Mask and the associated Applicator.<br><br>It has been identified that for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a potential risk of eye injury.<br><br>Johnson & Johnson (Ireland) Limited has issued two field safety notices (FSNs) one aimed at retailers and one targeted at consumers. These FSNs recommend users cease use of the Neutrogena® Visibly Clear Light Therapy Acne Mask and the associated Applicator immediately and return them to their place of purchase.<br><br>Please see the accompanying FSNs for further details. |

## ACTION OR RECOMMENDATIONS

The HPRA advises that **consumers**:

1. Refer to the accompanying consumer FSN and follow the instructions provided.
2. Stop using these products and return the affected products to the store where they were purchased from.
3. If you have any health concerns, please contact a healthcare professional.
4. Report any concerns regarding these devices or any adverse incidents involving these devices to Johnson & Johnson (Ireland) Limited and the HPRA.

The HPRA advises that **wholesalers / distributors / pharmacies / retail outlets**:

1. Refer to the accompanying FSNs and follow the instructions provided.
2. Check stock to determine whether affected product is in your possession.
3. If so, immediately quarantine and discontinue sale of the affected products.
4. Ensure that affected product is returned to the wholesaler / manufacturer.
5. Forward a copy of this Safety Notice and the FSNs to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
6. Report any concerns regarding these devices or any adverse incidents involving these devices to Johnson & Johnson (Ireland) Limited and to the HPRA.

## TARGET GROUPS

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|---|---|
| General public<br>Pharmacies<br>Dermatologists<br>Optometrist | Retail outlets<br>General Practitioners<br>Ophthalmologists |

## BACKGROUND

The Neutrogena® Visibly Clear Light Therapy Acne Mask is a reusable device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and a detachable corded activator. This is a home-use, over-the counter product which delivers a combination of Red and Blue light via light-emitting diodes (LEDs). The Neutrogena Visibly Clear Light Therapy Acne Mask Activator is designed to be combined with the Light Therapy Acne Mask. This is a single pack that is a replacement for when the original Activator runs out.

Johnson & Johnson (Ireland) Limited has become aware of a number of reports of visual effects associated with use of the Neutrogena® Visibly Clear Light Therapy Acne Mask. Johnson & Johnson (Ireland) Limited has indicated these reports are rare, generally mild and transient. However, for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a potential risk of eye injury.

Based on this, Johnson & Johnson (Ireland) Limited has made the decision to remove these devices from the market.

Johnson & Johnson (Ireland) Limited is recommending consumers cease use of the devices, and return them to the place of purchase. Should consumers experience any adverse effects they should contact their Healthcare Professional and report the incident to Johnson & Johnson (Ireland) Limited and to the HPRA using the contact information below.

In addition, retailers and distributors are instructed to cease any further sales of these devices, and to return them to Johnson & Johnson (Ireland) Limited.

As we are aware these devices are used by the general public, the HPRA is issuing this Safety Notice to highlight this issue to users, and raise awareness of the action being taken. In addition, there may have been additional devices supplied to the Irish market via online sales and international retailers.

## MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Johnson & Johnson (Ireland) Limited,
Airton Road,
Tallaght
Dublin 24

Telephone: 1-800-220044
E-mail: crc@its.jnj.com
Website: www.neutrogena.co.uk

## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie