

Date: 04.JUL.2019

## **Urgent Field Safety Notice** **Neutrogena Visibly Clear Light Therapy Acne Mask and** **Activator**

### **For Attention of Consumers**

### **Recall of NEUTROGENA® Visibly Clear Light Therapy Acne Mask and Activator**

#### **Affected Devices:**

Neutrogena Visibly Clear Light Therapy Acne Mask and Refill Activator

#### **Description of device and its intended application**

The Neutrogena Visibly Clear Light Therapy Acne Mask (Starter Kit, Model 31000) is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of Red and Blue light via light-emitting diodes (LEDs), and weighs less than 400g.

The Neutrogena Visibly Clear Light Therapy Acne Mask Activator (Model 71000) is offered separately to increase the number of doses available from the Neutrogena Visibly Clear Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries.

#### **Reason for Field Safety Corrective Action (FSCA)**

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask on the eye.

Our voluntary decision to recall this product has been taken out of an abundance of caution. Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask are rare, generally mild and transient. 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 theoretical risk of eye injury. The NEUTROGENA® Visibly Clear Light Therapy Acne Mask is safe for use by the general population when used as directed.

#### **Action to be taken by the user:**

This notice applies to all NEUTROGENA® Visibly Clear Light Therapy Acne Masks and Activators. This recall is being made with the knowledge and alignment of Health Products Regulatory Authority (HPRA). Consumers in Ireland should discontinue use immediately and return the devices to the place of purchase.

If consumers experience any adverse symptoms, they should contact their Healthcare Professional and report the incident to us at [crc@its.jnj.com](mailto:crc@its.jnj.com).

If consumers have any questions, they should speak to a Healthcare Professional or call 1-800-220044.

We apologize for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products.

#### **Contact reference person:**

The undersigned confirms that this notice has been notified to the HPRA  
Matthew Banwell – Head of Quality, Johnson & Johnson (Ireland) Limited, Airton Road, Tallaght, Dublin  
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