

Date: 04.JUL.2019

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

For Attention of Retailers

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

Dear Retailer/Pharmacist,

Out of an abundance of caution, Johnson & Johnson [Ireland] Limited has made the voluntary decision to recall the NEUTROGENA® Light Therapy Acne Mask and activator at wholesalers and retail stores, with a Consumer message via store, pharmacy and social media.

Affected Devices:

Neutrogena Visibly Clear Light Therapy Acne Mask and 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. However, if consumers have any concerns they should be instructed to stop use and consult their healthcare professional. Consumers may return NEUTROGENA® Visibly Clear Light Therapy Acne Mask to their place of purchase.

If a consumer reports an adverse experience with the product to you directly, please contact us immediately at crc@its.jnj.com so that we can investigate fully.

Actions to be taken:

Our records show that you have received one or more of the products subject to this voluntary recall. Please take the following actions:

1. Immediately review your inventory to identify and quarantine the affected products listed above in a manner that ensures the affected products will not be used.
2. Return the affected products. A credit note will be issued for the returned items.
3. If the affected products have been forwarded to another professional retailer, contact that retailer to arrange return to yourself.
4. Display a copy of the Consumer poster and the Consumer Urgent Field Safety Notice in your facility, if you are consumer facing.
5. Display a copy of the website notice and the Consumer Urgent Field Safety Notice, if you are selling via the web.
6. Maintain records of all returns and refunds.
7. Maintain awareness of this notice until the products have been returned.
8. Keep a copy of this notice.

Return:

Please return your stock to your supplier.

This product voluntary recall has been reported to the local competent authority and is being made with the knowledge and alignment with Health Products Regulatory Authority (HPRA).

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

Kind regards,



Matthew Banwell
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