
Urgent Safety Information

Costume, Information

regarding

Lic2 low impedance cream

27.11.2019

Sender:

SOMNOmedics GmbH
Am Sonnenstuhl 63
97236 Randersacker

Addressee:

To the users of Lic2 "low impedance cream".

Identification of the medical devices concerned:

LIC2 Adhesive electrode cream, water-based,

Item number: SEN035/1
SEN035

Ladies and Gentlemen,

SOMNOmedics GmbH strives for the highest quality of the products and services provided. Therefore, we would like to inform you about potential incidents when using the Lic2 electrode cream. During regular quality controls and market observations, the possible occurrence of the following isolated skin reactions was identified:

Reversible redness
Reversible skin irritations

when used in the facial area.

Which actions need to be taken by the addressee?

We ask you to clean the adhesive spots in the facial area only with alcohol and to refrain from using abrasive cleaning agents on the face.

For hypersensitive patients, the use of Ag/AgCl adhesive electrodes [e.g. item no.: SEN010C in combination with connection cables SEN018] is recommended.

Passing on the information described here:

Please ensure in your organisation that all users of the above products and other persons to be informed are aware of this "Urgent Safety Information". If you have provided the products to third parties, please forward a copy of this information or contact the person listed below. Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

We apologize for any inconvenience you may experience and hope this information will assist you in using Lic2. If you have any questions or require further information, please contact our customer service.

Contact:

SOMNOmedics Service

Phone: +49 931 / 35 90 94- 994 (Mo.-Fr. 8:00-24:00 o'clock)

Mail: service@somnomedics.de

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