

Safety Notice

Medical Devices

ThermaCare Lower Back & Hip Heatwraps

Priority 2 – Warning



HPRA Safety Notice: SN2019(18)

Issue Date: 27th May 2019

MANUFACTURER	HPRA CASE REFERENCE
Pfizer Consumer Healthcare	V39997

ISSUE
<p>Pfizer has identified that globally five lots of ThermaCare Lower Back and Hip Heatwraps may reach a higher temperature than specified (Lot numbers S23902, N3357, S00639, S97473 and W37940). Affected lots pose a potential risk of skin injury including burns/blisters and or skin irritation. The HPRA understands that only lot S23902 has been supplied to the Irish Market. For lot S23902, there is a risk that the temperature reached by individual heat cells within these wraps may exceed the normal temperature by 0.9°C, thus increasing the potential risk of thermal injury. However, the overall patient risk has been assessed by Pfizer as 'low'.</p> <p>Lot S23902 was distributed in Ireland between 12th September 2017 and 4th October 2017. Pfizer is recalling remaining stock to wholesaler level.</p> <p>The HPRA recommends that pharmacies/retail organisations and users determine if they have any unused ThermaCare Lower Back and Hip Heatwraps from the affected lot. If identified, we</p>

recommend no further distribution or use of this lot and to contact the supply source or the point of purchase for replacement stock.

Please refer to the accompanying field safety Notice (FSN) for further details.

ACTION OR RECOMMENDATIONS

The HPRA advises that wholesalers

1. Refer to the accompanying FSN and follow the instructions provided.
2. Acknowledge receipt of the FSN if you have not already done so.
3. Forward a copy of this safety notice and the FSN to all relevant personnel within your organisation.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

The HPRA advises that pharmacies/retail organisations

1. Inspect stock to determine if there is any remaining product from lot S23902.
2. Do not further distribute any product from lot S23902.
3. Contact the supply source or point of purchase to arrange for replacement stock.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

The HPRA advises that users:

1. Check if you have received product from lot S23902.
2. Do not use product from lot S23902.
3. Contact the point of purchase, (where you bought the product from), to arrange for replacement stock.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Carers	Nursing Homes
Community Pharmacists	Retail Organisations
General Practitioners	Risk Managers,
Members of the Public	Supplies Managers

BACKGROUND

Pfizer has identified that the affected lots may contain Heatwraps with individual heat cells reaching a higher temperature than specified. Pfizer is recalling impacted lots of the device to wholesaler level. The manufacturer has indicated that only Lot S23902 has been distributed in Ireland.

Pfizer is not aware of any adverse events involving this specific lot in Ireland, however due to the increased risk of thermal injury with the affected lot and as these devices have an expiry date of April 2020 the HPRA is recommending that the affected lot is not further distributed or used. The FSN applies only to the Thermacare Lower Back & Hip Heatwraps (pack of 2 wraps), Lot S23902 and not to any other pack size or lot number.

The HPRA is issuing this safety notice to raise awareness of this issue.

MANUFACTURER CONTACT INFORMATION

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

Pfizer Healthcare Ireland on behalf of
Pfizer Consumer Healthcare
9 Riverwalk, National Digital Park, Citywest
Business Campus
Dublin 24

Telephone: +353-1-4676627
E-mail: IEPCHRegAffairs@pfizer.com

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
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie