



URGENT FIELD SAFETY NOTICE: ThermaCare Lower Back & Hip Heatwraps information

May 21st, 2019

ThermaCare® Lower Back & Hip Heatwraps

Product Name	Lot Number	Expiration Date	SKU	UPC	Configuration/Count
ThermaCare® Lower Back and Hip Heatwraps (2 Count)	S23902	30-April- 2020	F00573301020A	5 000309 006463	4 (Case size)

Dear ThermaCare Wholesaler:

Pfizer Healthcare Ireland is initiating a voluntary wholesale level recall of **ThermaCare® Lower Back and Hip Heatwraps**, lot S23902, distributed in Ireland from 12.09.2017 to 04.10.2017.

We cannot ensure that the affected lot does not contain heatwraps with heat cells reaching a higher temperature than specified.

The use of heat cell wrap with increased temperatures poses a potential risk of skin injuries such as burns/blisters and/or skin irritation on the wrap-applied area. The product label recommends that the consumer stop use or wear a layer of clothing if the product feels too hot in order to prevent burns.

These label instructions are intended to mitigate risk of serious events. The potential risk to a consumer arising from this issue is considered to be low.

Instructions for Wholesalers: Our records indicate that you may have received shipment of the affected lot between **12.09.2017 and 04.10.2017**. Please check your stock immediately. If you have any unit of the affected lot in your inventory, please stop further distribution immediately and promptly return it to United Drug Distributors Magna Drive, Magna Business Park, Citywest Road, Dublin 24. You will receive credit from Pfizer Healthcare Ireland **only for the affected lot number**.

This recall is being conducted with the knowledge of the Health Products Regulatory Authority (HPRA). This action is being taken at Wholesalers only as agreed with the HPRA, however in the event that you receive



returns from the lot S23902 from your pharmacy customers, Pfizer Healthcare Ireland will proactively accept this product and you will receive a credit as well. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you. If you have any questions regarding the product, please contact the Pfizer Healthcare Ireland Information Line at 01 467 6627 (Mon.-Fri. 9 am-5 pm).

Sincerely,

Luis Gomez
Business Unit Lead & Commercial Director
PCH Ireland

Colm O'Connor
Pharmacy Sales Manager
PCH Ireland