

28th January 2022

Medicareplus International Company Statement Fire Risk within the Total Barrier Protection Range

Based on recent evaluation data, the Medicines and Health Regulatory Authority (MHRA) have issued guidance on the fire risk and risk of serious or fatal burns associated with emollient products both containing paraffin and those that are paraffin-free. The MHRA states that although emollients are not flammable in themselves or when on the skin, they can act as an accelerant, increasing the speed of ignition and intensity of the fire when fabric with residue dried on it is ignited. In association with the MHRA, the Commission on Human Medicines (CHM) has advised that due to the very rare risk, the modifiable risk factors, and their important therapeutic role, the benefits of using emollient products continues to outweigh the risk and should continue to be used.

In response to the above, Medicareplus International has performed a risk assessment of the Total Barrier Protection Product Range and, as a precautionary measure due to products having emollient properties, a warning statement in line with the CHM and MHRA guidance will be applied to the product labelling.

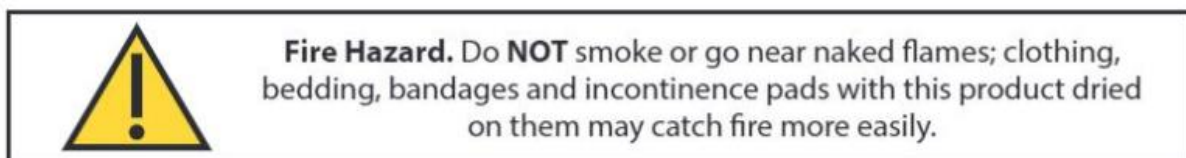
The products which fall under the scope of recent guidance are:

- Medi Derma-S Barrier Cream
- Medi Derma-Pro Skin Protectant Ointment.

In accordance with the advice provided by the CHM and MHRA to minimise risk and improve patient safety, Medicareplus International have implemented updates to the Instructions for Use Leaflets and product labelling of both products to include the below warning statement, which will be effective from April 2022.

Warning: Fire Hazard.

- **Do NOT smoke or go near naked flames; clothing, bedding, bandages and incontinence pads with this product dried on them may catch fire more easily.**
- **Fabrics (clothing, bedding, bandages, incontinence pads) that have been in contact with the product may ignite more easily, increasing the risk of serious burn injury.**
- **Frequent washing of clothing and bedding is advised to reduce the build-up of dried dried-on product, but this may not totally remove it, so extra caution is required.**



Further advice and resources for reducing risk when using emollient products can be found here: <https://www.gov.uk/guidance/safe-use-of-emollient-skin-creams-to-treat-dry-skin-conditions>

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