Press release: Alert to users of FreeStyle Libre flash glucose monitoring system regarding skin reactions to sensor adhesive

The Medicines and Healthcare products Regulatory Agency (MHRA) is aware some users of the FreeStyle Libre flash glucose monitoring system are experiencing skin reactions to the sensor adhesive.

Users may have been applying creams, sprays or patches under their sensor to reduce symptoms of skin reactions caused by the sensor adhesive. This is not advised as it may affect the performance of the device.

If you notice redness, itching or blistering, seek guidance from a healthcare professional on continuing the use of the device. They can advise on possible alternative glucose monitoring systems.

The manufacturer, Abbott, has confirmed they have revised the formulation of the adhesive, which will be available to customers in the UK from April 2019.

This problem may not be unique to the Abbott FreeStyle Libre sensor adhesive. The same actions should be taken if users experience similar symptoms with a different brand of continuous glucose monitoring system.

John Wilkinson, MHRA Director of Devices, said:

> It is important people can rely on their medical devices.
>
> If you experience skin irritation after applying the sensor of your flash glucose monitoring system you should speak with your doctor, pharmacist or diabetes management team.
>
> We continue to encourage people to report any issues involving medical devices to us via our Yellow Card Scheme.

Libby Dowling, Senior Clinical Advisor at Diabetes UK, said:

> People with diabetes who use flash should be aware that, as per recent reports, using barrier creams or sprays could affect the performance of their glucose monitoring sensors. If people are having skin reactions, they should consult with their healthcare professional or pharmacist in order to get advice on the measures they should take for the performance of their device to not be affected.

We’re reassured that the manufacturer is currently revising the formulation of the adhesive and is looking to make this available to the public in response.

Notes to editor

1. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.
2. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes NIBSC and CPRD. The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health and Social Care.
3. Anyone who has experienced an adverse incident with a medicine or medical device is encouraged to report any issues to MHRA via our Yellow Card Scheme.
4. Read the Medical Device Alert in full on our website.