

## **Urgent field safety notice**

May 2018

### **Important information on selected lots of Accu-Chek® Aviva (50s, 10s) and Accu-Chek® Performa (10s) strips potentially showing an increased number of strip errors prior to dosing or biased results**

Dear Healthcare Professional,

At Roche Diabetes Care we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of our products. This is why we would like to inform you today about an issue that might occur in certain lots of the Accu-Chek Aviva and Accu-Chek Performa test strips.

As part of our ongoing quality monitoring and market surveillance processes, we have identified certain test strip lots that potentially show an increase in strip errors prior to dosing. Due to the designed fail-safe in the blood glucose meter, the issue can be identified by an error message displayed on the meter upon strip insertion or through the device not recognising the test strip. However, in a very limited number of cases the test strip can produce a biased result i.e. a falsely too high or too low value, which your patients might not be able to detect easily and which could lead to erroneous therapy adaptations.

The affected UK products are:

Accu-Chek Aviva 50s

Accu-Chek Aviva 10s (Sold in retail only)

Accu-Chek Performa 10s (Sold in retail only)

Accu-Chek Performa 10s contained with Accu-Chek Performa Nano meter kits

As patient safety is our first priority, we would therefore like to ask you to advise your patients to:

- check the lot numbers of their test strip supplies against the complete list of lot numbers in Appendix A. You can also do this online by visiting [www.accu-chek.co.uk/customer-service/field-safety-notice](http://www.accu-chek.co.uk/customer-service/field-safety-notice). They can find the lot number on the top flap of the vial carton packaging as well as on the label of each test strip vial as shown in the picture below.



- discontinue using strips from the affected lots immediately and please return them to the pharmacy or store where they obtained the strips for a replacement pack at no charge.

Please check for any affected strip lots within your centers:

- Strips within the Accu-Chek Aviva Expert and Accu-Chek Performa Nano meter kits
- Accu-Chek Aviva 50s and 10s
- Accu-Chek Performa 10s

Please use other testing supplies to monitor your patients' glucose levels and contact your local sales representative to receive instructions on how to replace the products at no charge.

Please also complete and return the acknowledgement form on behalf of your center within 7 days of receipt of this notification.

We have thoroughly investigated this issue to identify the root cause of this potential error and have already started to implement the appropriate corrective measures. Please be assured that this issue only affects specific lots of the Accu-Chek Aviva and Accu-Chek Performa test strips. **Other Accu-Chek blood glucose test strips available in your market are not impacted by this issue.**

The MHRA, users of the affected blood glucose monitoring systems, distributors and retailers will all be informed about this field action.

Please call your local sales representative if you need any additional advice on the operation of Accu-Chek blood glucose meters and test strips, or have any further questions or concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions. We appreciate your time and attention to this important notification.

Kind regards,

Roche Diabetes Care

Appendix A: List of affected lot numbers

## **APPENDIX A: AFFECTED LOTS UK**

### **ACCU-CHEK AVIVA STRIPS (50s)**

- 497392
- 497391
- 496915
- 496809
- 496802
- 496807

### **ACCU-CHEK AVIVA STRIPS (10s)**

- 497344
- 497392

### **ACCU-CHEK PERFORMA STRIPS (10s)**

- 476597
- 476646

Accu-Chek Performa Nano mmol Kit. [Please note that the FSN only applies to the pack of Performa 10 test strips contained within the kit]

- 10153116
- 10153114
- 10153115
- 10153112
- 10153111

\*Our records indicate that you may have received stock from these specific affected lots.