Urgent Recall for Product Correction

April 17, 2014
Roche Ref.SB_RDC_2014_02
TGA Ref RC-2014-00438-1

Update to the product labelling

Accu-Chek® Mobile

To Accu-Chek Mobile users,

With this letter we would like to notify you that Roche Diabetes Care has become aware of a limitation of Accu-Chek® Mobile glucose tests, which may lead to erroneously lowered blood glucose readings in patients undergoing ceftriaxone therapy.

This antibiotic substance is used to treat a variety of infections such as respiratory infections or lower urinary tract infections and is only administered intravenously or intramuscularly. The interference is due to the effect this antibiotic has on the way the device measures the blood glucose. This limitation is not described in the product labeling.

Patients with diabetes who are receiving this therapy with ceftriaxone could be using the affected blood glucose monitoring (bGM) system.

If this is the case then we recommend you obtain an alternative bGM system for the duration of this therapy which is available from Roche Diabetes Care for free.

Roche Diabetes Care has immediately initiated all necessary measures to inform all relevant consignees and customers and to modify the labeling of the affected tests and test strips as soon as possible. The Therapeutic Goods Administration has been notified about this issue.

Roche Diabetes Care reassures all customers that for patients who are not receiving this specific antibiotic therapy, which is closely monitored by a healthcare professional, the use of Accu-Chek® blood glucose monitoring systems in compliance with the labeling is safe and the results obtained are accurate and reliable.

We thank you for your understanding and your cooperation.

Please do not hesitate to contact us on 1800-251-816 if you require further information.