



HCP Letter_Urgent Field Safety Notice

April **xx**, 2014

Roche Ref.SB_RDC_2014_02

Important Product Information for HCPs

Accu-Chek® Compact test strips & Accu-Chek® Mobile tests

Dear Healthcare Professional,

With this letter we would like to notify you that Roche Diabetes Care has become aware of a limitation of Accu-Chek® Compact test strips and Accu-Chek® Mobile tests, which may lead to **erroneously lowered** blood glucose readings in patients undergoing ceftriaxone therapy (e.g. Rocephin® or Cefotrix®). 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. This limitation is not described in the product labeling.

Patients with diabetes who are receiving this specific therapy should stop using both affected blood glucose monitoring (bGM) systems and obtain an alternative bGM system for the duration of this therapy. Roche Diabetes Care offers such an alternative by means of its bGM systems Accu-Chek® Aviva, Accu-Chek® Aviva Nano, Accu-Chek® Performa, Accu-Chek® Performa Nano, Accu-Chek® Inform, Accu-Chek® Inform II, and Accu-Chek® Aviva Expert.

To ensure a maximum patient safety, Roche Diabetes Care kindly asks you:

- To identify all patients who receive therapies containing the antibiotic substance ceftriaxone;
- To advise these patients not to use Accu-Chek® Compact test strips or Accu-Chek® Mobile tests throughout the duration of treatment with ceftriaxone and to provide an alternative bGM system (see above listed systems);

As patient safety is our top priority, Roche Diabetes Care has immediately initiated all necessary measures to inform all relevant consignees and to modify the labeling of the affected tests and test strips as soon as possible. The competent authority in your country 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. We apologize for any inconvenience this issue may cause. Please do not hesitate to contact the Accu-Chek® customer care line on **XX-XXX-XXXX** should you have any questions.

Sincerely,

Roche Diagnostics



Annex 1

URGENT FIELD SAFETY NOTICE

Acknowledgement Form

Roche Diagnostics Ref.: SB_RDC_2014_02

Herewith I acknowledge receipt of the Field Safety Notice of xx. April, 2014 concerning ceftriaxone interference issue with Accu-Chek® Compact test strips and Accu-Chek® Mobile tests.

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Please submit this acknowledgement form to Roche Diagnostics via e-mail; or fax:; or postal address:.....

Name of person completing this form: Title:.....

Company:

Phone #:..... Email:.....

Address:.....

Date: Signature.....

Thank you!