



# ***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



# 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!



## ***Distributor Letter\_Urgent Field Safety Notice***

April **xx**, 2014

Roche Ref.SB\_RDC\_2014\_02

### **Important Product Information for Distributors**

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

Dear Distributor / Retailer / Wholesaler...

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 preventively inform all healthcare professionals and any further distribution organization where Accu-Chek® Compact Plus and Accu-Chek® Mobile systems have been distributed to about the ceftriaxone interference.
- To recommend healthcare professionals alternative bGM systems such as the Accu-Chek® Aviva or Accu-Chek® Performa systems for the time their patients are receiving this specific treatment with ceftriaxone as these systems are not affected by this issue and their use is safe and reliable, if used as directed.

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



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Company: .....

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

Address:.....

Date: ..... Signature.....

Thank you!