

# Medical Device Alert

Ref: MDA/2014/026 Issued: 09 July 2014 at 11:30

## Device

Home use blood glucose meters:  
 Accu-Chek Compact meter and test strips  
 Accu-Chek Mobile meter and test cassette  
 Accu-Chek Active meter and test strips manufactured by Roche.

## Problem

The Accu-Chek Compact, Accu-Chek Mobile and Accu-Chek Active devices may give falsely low blood glucose readings for patients receiving ceftriaxone therapy.

Roche has updated product leaflets for these devices and issued a [Field Safety Notice \(FSN\)](#), distributed to healthcare professionals.

## Action

- Identify diabetic patients on ceftriaxone therapy.
- Advise these patients and relevant healthcare staff not to use Accu-Chek Compact, Accu-Chek Mobile or Accu-Chek Active devices throughout the duration of treatment with ceftriaxone.
- Ensure that patients on ceftriaxone therapy use an alternative device during their treatment.

## Action by

Healthcare personnel managing patients who use these devices.  
 Pharmacists.  
 Consultant microbiologists.  
 Outpatient antibiotic teams.

## CAS deadlines

Action underway: 16 July 2014  
 Action complete: 11 August 2014

**These deadlines are for staff and patients to be aware of the problem and of the advice recommended by the manufacturer in the FSN.**

## Contact

**Manufacturer**  
 Roche Diagnostics GmbH  
 Accu-Chek Careline:  
 Tel: 0800 701 000

## Device



Accu-Chek Compact meter

Accu-Chek Active meter

Accu-Chek Mobile meter

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Social services in England (directors)
- Special health authorities for information

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.

Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All wards
- Ambulance services directors
- Ambulance staff
- Biomedical science departments
- Chief pharmacists
- Clinical governance leads
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Dietetics departments
- District nurses
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists

- NHS walk-in centres
- Outpatient clinics
- Paediatricians
- Paediatrics departments
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Podiatrists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- School nurses
- Walk-in centres

### **NHS England area teams**

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- Practice managers
- Practice nurses

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house residential care homes

### **Independent distribution**

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

#### **Establishments registered with OFSTED**

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **Manufacturer**

Roche Diagnostics GmbH

Accu-Chek Careline:

Tel: 0800 701 000

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/026** or **2014/004/011/081/010**.

### Technical aspects

Mrs Sonal Vara or Mrs Bina Mackenzie  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7710 / 7229

Fax: 020 8754 3965

Email: [sonal.vara@mhra.gsi.gov.uk](mailto:sonal.vara@mhra.gsi.gov.uk)  
[bina.mackenzie@mhra.gsi.gov.uk](mailto:bina.mackenzie@mhra.gsi.gov.uk)

### Clinical aspects

Dr Camilla Fleetcroft  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 6097

Email: [camilla.fleetcroft@mhra.gsi.gov.uk](mailto:camilla.fleetcroft@mhra.gsi.gov.uk)

### How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6

Castle Buildings, Stormont Estate  
Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team  
Medical Directorate  
Welsh Government  
Cathays Park  
Cardiff CF10 3NQ

Tel: 029 2082 5801

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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