1 Sabax Road, Aeroton, Johannesburg, 2013, South Africa
P O Box 6888, Johannesburg, 2000, South Africa
Telephone: +27 11 494 8000
Telefax: +27 11 494 1911
Email: adcock.criticalcare@adcock.com
Docex No 2 Aeroton
GPS Co-ordinates: S 26 15 22 52 E 27 58 53 06

www.adcock.com

04 November 2010

IMPORTANT

MEDICINE SAFETY INFORMATION

Patients receiving EXTRANEAL (icodextrin) for peritoneal dialysis therapy may have incorrect blood glucose reading when using particular blood glucose monitoring systems.

Dear Healthcare Professional,

Adcock Ingram Critical Care (Pty) Ltd., on behalf Baxter Healthcare Corporation would like to notify you of **important safety information** involving patients who use **EXTRANEAL** (icodextrin) peritoneal dialysis solution and who may require the use of blood glucose monitors and test strips.

Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific.
These methods are common in clinical laboratories. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. For further information, visit www.glucosesafety.com for additional information, including a glucose monitor compatibility list.

The term "glucose-specific" applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **EXTRANEAL** (icodextrin) peritoneal dialysis solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used.

DO NOT use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method should not be used.

Use of these methods may result in falsely elevated blood glucose readings in patients using **EXTRANEAL** (icodextrin) due to maltose interference. A blood glucose reading with these monitors that appears to be within the normal range in a patient on **EXTRANEAL** (icodextrin) may mask true hypoglycemia (low blood sugar). This would cause a patient or health care professional not to take the appropriate steps to bring the blood sugar into a normal range. A falsely elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, neurological damage or death.

Additional considerations for patients who use **EXTRANEAL** (icodextrin):

1. Discontinuing **EXTRANEAL** (icodextrin) use will not immediately address the risk for the potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).

2. To determine what type of method is used for monitoring glucose levels, review the labelling for BOTH the glucose monitor and the test strips used. If in doubt, contact the manufacturer of the glucose monitors and test strips to determine the method that is used.

3. If your hospital uses electronic medical records, the above information describing the potential for interference with blood glucose monitors or test strips needs to be entered in a suitable field readily apparent to all users.

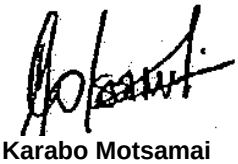
For further information, refer to **EXTRANEAL** (icodextrin) prescribing information or visit ***www.glucosesafety.com.***

The package insert of EXTRANEAL (icodextrin) is in the process of being reviewed to reflect this safety information.

We trust that we have informed you adequately, but if you have any additional questions about **EXTRANEAL** (icodextrin), please do not hesitate to contact us.

Healthcare professionals should report all adverse events associated with the use of **EXTRANEAL** to Adcock Ingram Critical Care by phone on 011 494 8429 or by fax on 011 494 1911, or alternatively to the NADEMC (National Adverse Drug Event Monitoring Centre) on telephone 021 447 1618 or fax 021 448 6181.

Yours faithfully



Karabo Motsamai
Group Regulatory Affairs and Clinical Manager
Adcock Ingram Critical Care (Pty) Ltd

Peter Rutherford MD PhD
Medical Director (Renal) Europe
Baxter International Inc

RSA101GLPST3

Adcock Ingram Critical Care (Pty) Ltd
Reg No 2000/004208/07
Directors: Mr V.N. Desai, Mrs K.J. Hampton, Mrs B.J. Letsoalo, Mr M.Y. Mangel
Company Secretary: Mrs R. Naidoo