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IMPORTANT

MEDICINE SAFETY INFORMATION

Patients receiving EXTRANEAL (Icodextrin 7,5 %) 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 7.5%) peritoneal dialysis solution and who may require the use of blood glucose monitors and test strips.

Patients using EXTRANEAL (icodextrin 7.5%) 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.glucosafety.com.

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 7.5%) peritoneal dialysis solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used. Glucose-specific monitors and test strips include glucose oxidase (GOD), hexokinase, glucose dehydrogenase with nicotinamide adenine dinucleotide (GDH-NAD), or glucose dehydrogenase with flavin-adenine dinucleotide (GDH-FAD) based methods.

DO NOT use glucose monitors or test strips that utilize the enzyme glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase. Maltose interferes with these glucose monitors and test strips, which may result in a falsely elevated blood glucose reading. This may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia. A blood glucose reading with these monitors within the normal range in a patient on **EXTRANEAL** (icodextrin 7.5%) may mask 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 7.5%):

1. Discontinuing **EXTRANEAL** (icodextrin 7.5%) use will not immediately address the risk for the potential interference with glucose monitors. Plasma levels of icodextrin and its metabolites require a minimum of 14 days to become undetectable.
2. To determine what type of method is used for monitoring glucose levels, review the labeling 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.

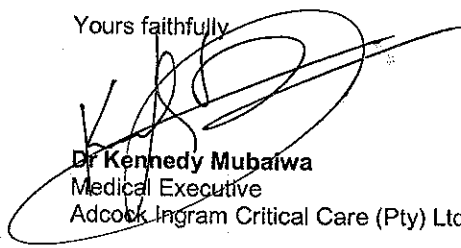
For further information, refer to **EXTRANEAL** (icodextrin 7.5%) prescribing information or visit www.glucosesafety.com.

The updated approved package insert of **EXTRANEAL** (Icodextrin 7,5 %) reflecting this safety information is attached.

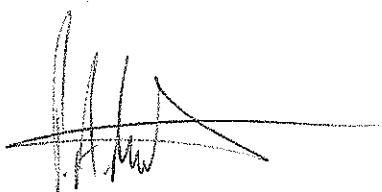
We trust that we have informed you adequately, but if you have any additional questions about **EXTRANEAL** (Icodextrin 7.5%), please do not hesitate to contact us.

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



Dr Kennedy Mubaiwa
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