

## Attention Healthcare Professional

### WARNING

#### Potential for Incorrect Blood Glucose Reading

May 26<sup>th</sup>, 2024

Dear Healthcare Professional,

Vantive Health LLC 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 who use 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. Visit [www.glucosafety.com](http://www.glucosafety.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 to avoid false readings.

**DO NOT use glucose monitors or test strips that utilise glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase methods. In addition, some but not all monitors or test strips that utilise 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 hypoglycaemia. 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 potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).

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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.

Suspected Adverse Drug Reactions (side effects) or medication errors should be reported to Vantive at [UK.Ireland.GPS.drugsafety@vantive.com](mailto:UK.Ireland.GPS.drugsafety@vantive.com) and to the local Authority using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>, and sent by post or email to;

**P:** Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

**E:** [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

For further information, please refer to **EXTRANEAL** (icodextrin) prescribing information or visit [www.glucosesafety.com](http://www.glucosesafety.com).

I hope this information is helpful to you. If you have additional questions about **EXTRANEAL** (icodextrin), please contact your Vantive Renal Representative.



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