

Polithera (icodextrin)

Solution for peritoneal dialysis

This material is important information on minimising the risk of falsely elevated glucose readings due to use of GDH-PQQ-, GDO-, or some GOH-FAD-based glucometers and test strips.

This is important information for
Healthcare Professionals

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Warning!

Potential for Incorrect Blood Glucose Reading

Dear Healthcare Professional,

Vivisol srl would like to notify you of **important safety information** involving patients who use **Polithera** (icodextrin) peritoneal dialysis solution and who may require the use of blood glucose monitors and test strips.

Patients who use Polithera (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 additional safety information, regarding Polithera, a compatibility list is available on the website <https://www.glucoseinformation.it>

The term “glucose-specific” applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **Polithera** (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 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 **Polithera** (icodextrin) due to maltose interference.

A blood glucose reading with these monitors that appears to be within the normal range in a patient on **Polithera** (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 Polithera (icodextrin):

1. Discontinuing **Polithera** (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 **Polithera** (icodextrin).

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. The above information describing the potential for interference with blood glucose monitors or test strips needs to be entered in a suitable field readily visible to all users.

*For further information, please refer to **Polithera** (icodextrin) prescribing information.*

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