

March 2021

Urgent Product Defect Correction: Dexcom CGM Systems

TGA Ref: RC-2021-RN-00191-1

Dexcom recently became aware that **hydroxyurea**, an anti-neoplastic drug used primarily in chemotherapy, **falsely elevates glucose readings on Dexcom CGM systems**. This may result in failure to treat hypoglycaemia from missed low sensor glucose values and alerts or by causing other errors in diabetes management decisions.

Some examples of the disease states that hydroxyurea is more commonly used in include:

- Chronic Myelogenous Leukaemia (CML)
- Head and neck malignancies, and
- Sickle cell disease

Dexcom is currently updating their Instructions For Use precautionary information as follows:

- **Dexcom G4 PLATINUM** - *If you are taking hydroxyurea, your readings may be falsely elevated and result in missed hypoglycaemia alerts. The level of inaccuracy depends on the amount of hydroxyurea in your body.*
- **Dexcom G5 Mobile** - *If you are taking hydroxyurea, your Dexcom G5 Mobile readings may be falsely elevated and result in missed hypoglycaemia alerts or errors in diabetes management decisions. The level of inaccuracy depends on the amount of hydroxyurea in your body. Use your meter.*
- **Dexcom G6** - *If you are taking hydroxyurea, your Dexcom G6 readings may be falsely elevated and result in missed hypoglycaemia alerts or errors in diabetes management decisions. The level of inaccuracy depends on the amount of hydroxyurea in your body. Use your meter.*

Requested Action:

Please go to [surveymonkey.com/r/dexcom-hydroxyurea-correction-notice](https://www.surveymonkey.com/r/dexcom-hydroxyurea-correction-notice) to complete a short online form to confirm that you have received this important communication. If you cannot complete this form, simply email amsl.regulatory@amsl.com.au confirming receipt.

Should you have any questions regarding how this notice might affect you, please contact our AMSL Diabetes 24/7 Customer Care Team on 1300 851 056 or diabetes@amsl.com.au. Alternatively, you can contact your local AMSL Diabetes Representative.