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**IMPORTANT MEDICINE
SAFETY INFORMATION**

APPROVED
BY THE

HPRA



An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

20th September 2024

Hydroxycarbamide-containing medicinal products: Potential interference with continuous glucose monitoring systems

Dear Healthcare professional,

CHEPLAPHARM Arzneimittel GmbH in agreement with the Health Products Regulatory Authority would like to inform you of the following:

Summary

- **Hydroxycarbamide may falsely elevate sensor glucose results from certain continuous glucose monitoring (CGM) systems which may lead to hypoglycaemia if sensor glucose results are relied upon to dose insulin.**
- **If CGM systems are to be used concurrently with hydroxycarbamide treatment, consult with the CGM prescriber about the need to consider alternative glucose monitoring methods.**

Background on the safety concern

Interference of hydroxycarbamide (also known as hydroxyurea) with certain continuous glucose monitoring (CGM) systems leading to falsely elevated glucose readings has been reported in the scientific literature ^{1, 2, 3}.

CGM systems are wearable sensors measuring glucose in the interstitial fluid based on selective oxidation at the sensor-electrode. The mechanism by which hydroxyurea could potentially interfere with CGM systems is not proven but it is possibly directly oxidised at the electrode falsely elevating the test results. CGM systems that are available in Ireland include products from Dexcom (Dexcom G6, G7, One+), Abbott Diabetes Care (FreeStyle Libre), Medtronic (Medtronic Guardian™ Sensor), and Windzor Pharma Ltd (GlucoRx Aidex™).

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) recommended that the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of hydroxycarbamide-containing products should be updated to include a warning about the risk of interference with CGM systems leading to hypoglycaemia if sensor glucose results are relied upon to dose insulin.

Hydroxycarbamide-containing medicinal products are authorised in haematological and oncological indications in Ireland. These products include Hydrea 500 mg Hard Capsules which is indicated in the management of malignant neoplastic disease including chronic myeloid leukaemia (pretreatment phase and palliative care) and is also indicated for treatment of cancer of the cervix and other solid type tumours in conjunction with radiotherapy.

If CGM systems are to be used concurrently with hydroxycarbamide treatment, the CGM prescriber should be consulted about the need to consider alternative glucose monitoring methods.

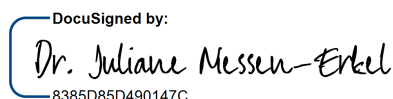
Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Company contact point

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Yours faithfully,


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Annexes

List of literature references

1. Conti M, Meneghini E, Fumagalli G, Guidoni F, Bertuzzi F, Pintaudi B. Severe hypoglycemia caused by hydroxyurea interference on continuous glucose sensor integrated with advanced hybrid closed-loop system: a case report. *Acta diabetologica*. 2023.
2. Szmuiłowicz ED, Aleppo G. Interferent Effect of Hydroxyurea on Continuous Glucose Monitoring. *Diabetes Care*. 2021;44(5):e89-e90.
3. Tellez SE, Hornung LN, Courter JD, Abu-El-Haija M, Nathan JD, Lawson SA, et al. Inaccurate Glucose Sensor Values After Hydroxyurea Administration. *Diabetes Technol Ther*. 2021;23(6):443-51.