

Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for hydroxycarbamide (except for centrally authorised product), the scientific conclusions are as follows:

In view of available data on interference of hydroxycarbamide with CGM systems, from the literature, including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between hydroxycarbamide and falsely high CGM sensor glucose readings leading to hypoglycaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing hydroxycarbamide should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for hydroxycarbamide (except for centrally authorised product) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing hydroxycarbamide (except for centrally authorised product) is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.4

Interference with Continuous Glucose Monitoring Systems

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.

Package leaflet

- **2. What you need to know before you <take> <use>**

Warnings and precautions

Talk to your doctor <or> <pharmacist> <or nurse> before <taking> <using> X

If you have diabetes and are using a continuous glucose monitor (CGM) to test your blood glucose. Hydroxycarbamide (also known as hydroxyurea) may cause falsely high sensor glucose readings from certain sensors. This could result in using more insulin than needed, leading to low blood sugar (hypoglycaemia). Talk to the physician that prescribed your CGM about whether it is safe to use while you are taking X.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	July 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	08 September 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	07 November 2024