22 February 2024
EMA/CHMP/56243/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xromi

hydroxycarbamide

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Xromi. The marketing authorisation holder for this medicinal product is Nova Laboratories Ireland Limited.

The CHMP adopted an extension to the existing indication to include prevention of sickle cell disease complications in infants from 9 months of age.

For information, the full indication will therefore be as follows[2]:

> Xromi is indicated for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over **9 months** ~~2 years~~ of age

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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