EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2019
EMA/CHMP/223395/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xromi

hydroxycarbamide

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xromi, intended for the prevention of vaso-occlusive complications of sickle cell disease in patients over 2 years of age. The applicant for this medicinal product is Nova Laboratories Ireland Limited.

Xromi will be available as a 100 mg/ml oral solution. The active substance of Xromi is hydroxycarbamide, a ribonucleotide reductase inhibitor (ATC code: L01XX05) which acts by interfering with the synthesis of DNA, without interfering with the synthesis of ribonucleic acid or protein.

The benefits with Xromi are its ability to reduce the vaso-occlusive complications of sickle cell disease. The most common side effects are bone marrow depression including neutropenia, reticulocytopenia, macrocytosis, thrombocytopenia, anaemia, headache, dizziness, nausea, constipation, skin ulcer, oral, nail and skin hyperpigmentation, dry skin and alopecia.

Xromi is a hybrid medicine[2] of Hydrea which has been authorised in the EU since 29 May 1986. Xromi contains the same active substance as Hydrea but is authorised for a different indication. Hydrea is authorised for the treatment of certain cancers.

The full indication is: "prevention of vaso-occlusive complications of sickle cell disease in patients over 2 years of age." It is proposed that Xromi be prescribed by a physician or other healthcare professionals experienced in the management of patients with sickle cell disease.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union