



hydroxycarbamide 100mg/mL oral solution (Xromi®)

Nova Laboratories Limited

10 July 2020

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following assessment under the abbreviated process

hydroxycarbamide oral solution (Xromi®) is accepted for restricted use within NHSScotland.

Indication under review: for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 2 years of age.

SMC restriction: children who are too young to be able to swallow capsules / tablets and adults and adolescents who have difficulty in swallowing solid oral dosage forms.

The availability of hydroxycarbamide oral solution (Xromi®) provides a licensed alternative to unlicensed liquid preparations.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 25 June 2020.

Chairman

Scottish Medicines Consortium