

01 March 2023

Hydroxycarbamide 100 mg/ml oral solution (Xromi[®]): Changes to the oral syringes co-packaged with Xromi[®]

Dear Healthcare Professional,

Nova Laboratories Limited, in agreement with SFDA, would like to inform you of the following:

Summary

We are writing to inform you of changes to the colour, volume and graduations of the oral syringes included in the Xromi[®] product packaging:

- ***Previously*** the packaging contained a small **3 ml** syringe (with **red** plunger and **0.1 ml** graduations) and a large **12 ml** syringe (with **white** plunger and **0.25 ml** graduations).
- ***New*** packaging contains a small **3 ml** syringe (with **violet** plunger and **0.1 ml** graduations) and a large **10 ml** syringe (with **violet** plunger and **0.5 ml** graduations).

Background on the safety concern

Xromi[®] is indicated for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 2 years of age.

The packaging contained a small 3 ml syringe (with red plunger and 0.1 ml graduations) and a large 12 ml syringe (with white plunger and 0.25 ml graduations).

The new packaging contains a small **3 ml** syringe (with **violet** plunger and **0.1 ml** graduations) and a large **10 ml** syringe (with **violet** plunger and **0.5 ml** graduations).





SyrChg3mlV001





The changes to the oral syringes were unavoidable due to disruption in the global supply chain.

The product information has been revised to describe these changes.

Please note that the change in volume graduations from 0.25 ml to 0.5 ml in the larger 10 ml syringe means that when Xromi[®] is initiated, doses greater than 300 mg will need to be prescribed in 50 mg increments.

For patients already established on Xromi[®] at doses greater than 300 mg but at 25 mg increments, their doses should be adjusted to 50 mg increments for future prescriptions. This corresponds to the nearest 0.5 ml syringe graduation.

Although the dose adjustments with the new syringe are expected to be clinically insignificant, the dose adjustment (rounding up or down to the nearest 0.5 ml syringe graduation) should be decided by the specialist. Doses less than 300 mg can continue to be prescribed with an accuracy of 10 mg increments.

It is important that healthcare professionals advise the patient or parent which syringe to use (3 ml or 10 ml) to ensure that the correct volume is administered.

We ask that you familiarise yourself with these changes, which are all reflected in updated Educational Materials for both you as a healthcare professional and for your patients.

Please also ensure that your patients are made aware of these changes at their next visit.

We are currently sourcing bespoke 10 ml syringes with 0.25 ml graduations, which should be available in late autumn 2023. Additional communication related to these bespoke syringes will be sent out closer to the time.

Call for reporting

To report any side effect(s):

- ***Saudi Arabia:***



- The National Pharmacovigilance Centre (NPC)

- Toll free phone: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: <https://ade.sfd.gov.sa/>

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Company contact point

If you have any medical questions in relation to Xromi[®] (Hydroxycarbamide), please contact Qomel directly on the email regulatory@qomel.com

Yours sincerely,

Hisham Alagla
Qualified person for Pharmacovigilance
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