

Xromi[®] (Hydroxycarbamide)

100 mg/ml oral solution

Patient/Parent Guide

Important safety information about serious side effects that you need to be aware of before, during and after treatment

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)

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1. Why your doctor has prescribed Hydroxycarbamide

Your doctor has prescribed Hydroxycarbamide for you or your child to treat a condition called Sickle Cell Disease. This is an inherited disease that affects the red cells of the blood. Some cells become abnormal, rigid and take a crescent or sickle shape which leads to anaemia. The sickle cells also get stuck in blood vessels, blocking blood flow. This can cause acute pain crises and organ damage.

Hydroxycarbamide is used to prevent the complications of blocked blood vessels caused by Sickle Cell Disease in patients over 2 years of age.

Hydroxycarbamide will decrease the number of painful crises as well as the need for hospitalisation as a result of the disease.

- ◇ Hydroxycarbamide has been prescribed for you. Never give it to someone else, even if he or she has the same disorder for which you are being treated.
- ◇ Take this medicine exactly as it has been prescribed for you by your doctor. Take your treatment regularly and do not change the dose yourself.

Hydroxycarbamide may interact with other medicines and live virus vaccines. Please tell your doctor if you are taking or have recently taken any other medicines, even those obtained without a prescription. Please tell your doctor if you have had or are due to have any vaccinations (e.g. measles, mumps, rubella (MMR), chicken pox).

Before starting the treatment, read the package leaflet present in each box of Hydroxycarbamide

2. Hydroxycarbamide must be handled with care

Please use the syringe as advised by your doctor or pharmacist.
Ask your doctor or pharmacist if you have any questions

Each pack contains one 150 ml bottle capped with a child-resistant closure, a bottle adaptor and two dosing syringes (a small syringe graduated to 3 ml and a large syringe graduated to 10 ml).



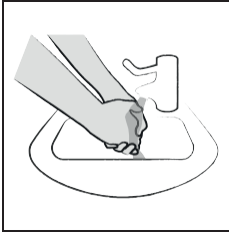
	Syringe Type	
Syringe volume	3 ml	10 ml
Colour	Violet	Violet
Measurements	0.5 ml to 3 ml	1 ml to 10 ml

Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed. Please make sure that you have fully understood the dosing instructions given to you by your doctor or pharmacist. If you are in any way uncertain, please contact your doctor or pharmacist to confirm your dosing instructions.

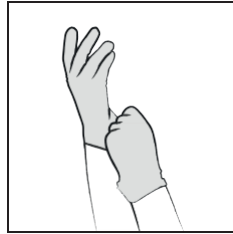
IMPORTANT

- ◇ **Women who are pregnant, planning to be or breastfeeding should not handle Hydroxycarbamide**
 - ◇ **Hydroxycarbamide may be taken with or after meals at any time of the day.** However, the choice of method and time of day should be consistent from day to day
 - ◇ **Water should be taken after each dose of Hydroxycarbamide to assist accurate and consistent dose delivery to the stomach**
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- ◇ Keep out of the sight and reach of children. Accidental ingestion can be lethal for children.
 - ◇ Store in a refrigerator (2 °C - 8 °C). After first opening of the bottle, discard any unused contents after 12 weeks.
 - ◇ Keep the bottle tightly closed to prevent spoilage of the medicine and reduce the risk of accidental spillage. To minimise air bubbles, the bottle should **not** be shaken prior to dosing.

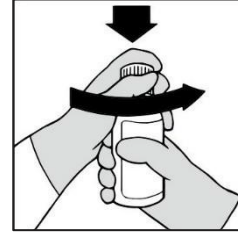
3. Handling



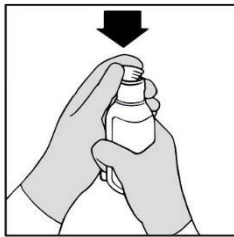
1. Wash your hands before and after administering a dose. Wipe up spillages immediately



2. Put on disposable hand gloves to decrease the risk of exposure



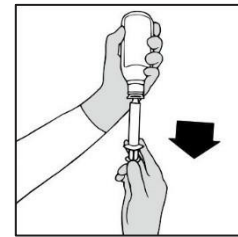
3. Remove the bottle cap



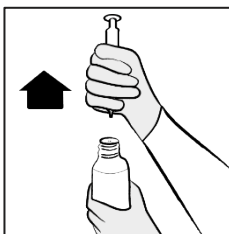
4. Push the adaptor firmly into the top of the bottle and leave in place for future doses



5. Push the tip of the dosing syringe into the hole in the adaptor. Your doctor or pharmacist will advise you of the correct syringe to use, either the 3 ml (small) syringe or the 10ml (large) syringe in order to give the correct dose



6. Turn the bottle upside down. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed



7. Turn the bottle back the right way up and carefully remove the syringe from the adaptor, holding it by the barrel rather than the plunger



8. Gently put the tip of the syringe into your mouth and to the inside of your cheek



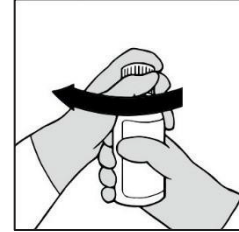
9. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek and swallow it. DO NOT forcefully push down the plunger, or squirt the medicine to the back of your mouth or throat, as you may choke



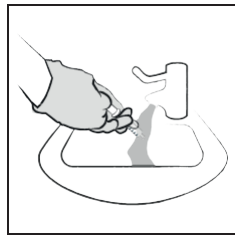
10. Remove the syringe from your mouth



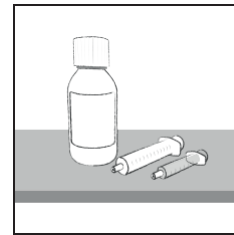
11. Swallow the dose of oral solution then drink some water, making sure no medicine is left in your mouth



12. Put the cap back on the bottle with the adaptor left in place. Ensure that the cap is tightly closed



13. Wash the syringe with cold or warm tap water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the syringe is clean. Let the syringe dry completely before you use it again



14. Store the medicine in a refrigerator (2 °C – 8 °C). Store the syringe(s) in a hygienic place

If you are not sure about how much medicine to draw into the syringe, always ask your doctor or nurse for advice.

Wash immediately and thoroughly with soap and water if Hydroxycarbamide comes into contact with skin, eyes or nose

4. Need for contraception

Do not take Hydroxycarbamide if you are planning to have a baby without first speaking to your doctor for advice. This applies to both men and women. Xromi may harm your sperm or eggs.

Talk to your doctor, nurse or pharmacist concerning the use of contraceptive measures before and during treatment with Hydroxycarbamide.

Hydroxycarbamide is an active substance which may cause changes to the DNA (mutagenic).

Hydroxycarbamide should be stopped 3 to 6 months prior to becoming pregnant, if possible.

The use of effective contraception before and during treatment is strongly recommended for both male and female patients

5. Risk to male fertility,

Hydroxycarbamide may decrease your ability to father children (fertility) while you are treated.

It is important for you to know that Hydroxycarbamide may decrease sperm production and harm your sperm.

Absence or low amount of sperm in the semen (azoospermia or oligospermia) is a very common side effect of Hydroxycarbamide. These disorders are also associated with the underlying disease. It has to be taken into account when fatherhood is desired.

Talk to your doctor or nurse if this is a concern for you. Your doctor can inform you about the possibility of sperm conservation (cryopreservation) before the start of therapy.

potential risk to foetus and breastfeeding

If you are a woman planning to become pregnant or are pregnant

Hydroxycarbamide can potentially cause foetal harm (birth defects) when administered to a pregnant woman, as it crosses the placental barrier.

Hydroxycarbamide must not be used during pregnancy.

If you become pregnant while you are still taking Hydroxycarbamide, please contact your doctor immediately.

Please contact your doctor immediately if you think you may be pregnant.

Breastfeeding

Hydroxycarbamide is excreted in human breast milk. You should not breastfeed during the treatment.

You should not handle Hydroxycarbamide if you are pregnant, planning to be or breastfeeding.

6. Side effects which have been observed with Hydroxycarbamide

Like all medicines, Hydroxycarbamide can cause side effects (although not everybody gets them). If you notice any side effects, please tell your doctor or pharmacist.

Reporting of side effects

You can also report side effects directly to the Health Products Regulatory Authority.

At:

To report any side effect(s):

- Saudi Arabia Saudi Food And Drug Authority
 - The National Pharmacovigilance Centre (NPC) :
 - Toll free phone: 19999
 - E-mail: npc.drug@sfd.gov.sa
 - Website: <https://ade.sfda.gov.sa/>

Or

- Qomel Co Ltd reporting contact
 - Fax: +966-11-288-6668
 - Phone Number: +966-11-288-6660
 - E-mail: regulatory@qomel.com

By reporting side effects, you can help provide more information on the safety of this medicine.

7. Patient Information Leaflet

The package leaflet (Patient Information Leaflet) is available at SFDA website: <https://sdi.sfda.gov.sa/>

Before starting treatment, please read the complete package leaflet and also for further information talk to your doctor, nurse or pharmacist if you have questions or concerns.