

Package leaflet: Information for the user

Xromi 100 mg/ml oral solution hydroxycarbamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xromi is and what it is used for
2. What you need to know before you take Xromi
3. How to take Xromi
4. Possible side effects
5. How to store Xromi
6. Contents of the pack and other information

1. What Xromi is and what it is used for

Xromi contains hydroxycarbamide, a substance which reduces the growth and multiplication of some cells in the bone marrow. These effects lead to a reduction of circulating red, white and coagulation blood cells. In Sickle Cell Disease, hydroxycarbamide also helps to prevent red blood cells from taking the abnormal sickle shape.

Sickle Cell disease is an inherited blood disorder that affects the disc shaped 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.

Xromi is used to prevent the complications of blocked blood vessels caused by Sickle Cell Disease in patients over 9 months of age. Xromi will decrease the number of painful crises as well as the need for hospitalisation as a result of the disease.

2. What you need to know before you take Xromi

Do not take Xromi

- if you are allergic to hydroxycarbamide or any of the other ingredients of Xromi (listed in section 6).
- if you suffer from severe liver disease
- if you suffer from severe kidney disease
- if you have decreased production of red, white, or coagulating blood cells ('myelosuppressed') as described in section 3 "How to take Xromi, Treatment follow-up"
- if you are pregnant or breast-feeding (see section "Pregnancy, breast-feeding and fertility").
- if you take antiretroviral medicines for the treatment of Human Immunodeficiency Virus (HIV), the virus which causes AIDS

Warnings and precautions

Test and checks

Your doctor will run blood tests:

- to check your blood count before and during treatment with Xromi
- to monitor your liver before and during treatment with Xromi
- to monitor your kidneys before and during treatment with Xromi

Talk to your doctor, pharmacist or nurse before taking Xromi

- if you have extreme tiredness, weakness and shortness of breath, which may be symptoms of a lack of red blood cells (anaemia)
- if you have bleeding or bruise easily, which may be symptoms of low levels of cells in the blood known as platelets
- if you have a liver disease (additional monitoring may be needed)
- if you have a kidney disease (the dose may be adjusted)
- if you have leg ulcers
- if you have a known lack of vitamin B₁₂ or folate

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Xromi.

Skin cancer has been reported in patients receiving long term hydroxycarbamide. You should protect your skin from the sun and regularly inspect your skin yourself during the treatment and after discontinuation of the therapy with hydroxycarbamide. Your doctor will also inspect your skin during routine follow-up visits.

Children

Do not give this medicine to children from birth to 9 months of age because it is unlikely to be safe.

Other medicines and Xromi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following:

- other myelosuppressive medicines (those that decrease production of red, white, or coagulating blood cells)
- radiation therapy or chemotherapy
- any medicines for cancer treatment, especially interferon therapy - when used with Xromi there is a greater chance of side effects, such as anaemia
- antiretroviral medicines (those that inhibit or destroy a retrovirus such as HIV), e.g. didanosine, stavudine, and indinavir (a drop in your white cell count may occur)
- live vaccines, e.g. measles, mumps, rubella (MMR), chicken pox

Pregnancy, breast-feeding and fertility

Do not take Xromi 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.

Xromi must not be used during pregnancy. Xromi should be stopped 3 to 6 months prior to becoming pregnant, if possible.

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

The use of effective contraception is strongly recommended for both male and female patients.

For male patients taking Xromi, if your partner becomes pregnant or plans to become pregnant, your doctor will discuss with you the potential benefits and risks of continuing using Xromi.

Hydroxycarbamide, the active substance of Xromi, passes into human breast milk. Do not breastfeed while taking Xromi. Ask your doctor or pharmacist for advice.

Driving and using machines

Xromi can make you feel drowsy. You should not drive or operate any machinery unless it has been shown not to affect you and you have discussed it with your doctor.

Xromi contains methyl parahydroxybenzoate (E218)

Xromi contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

3. How to take Xromi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Xromi should only be given to you by a specialist doctor who is experienced in treating blood problems.

- When you take Xromi your doctor will take regular blood tests. This is to check the number and type of cells in your blood and to check your liver and kidney.
- Depending on the dose you take, these tests may be performed initially once a month and then every 2-3 months.
- Depending on these results your doctor may change your dose of Xromi.

Check with your doctor or pharmacist if you are not sure. The usual starting dose for adults, adolescents and children over the age of 9 months is 15 mg/kg each day and the usual maintenance dose is between 20-25 mg/kg. Your doctor will prescribe the correct dose for you. Sometimes the doctor may change your dose of Xromi, for example as a result of different tests. If you are not sure how much medicine to take, always ask your doctor or nurse.

Xromi with food and drink

You can take this medicine 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.

Use in elderly

You may be more sensitive to the effects of Xromi and your doctor may need to give you a lower dose.

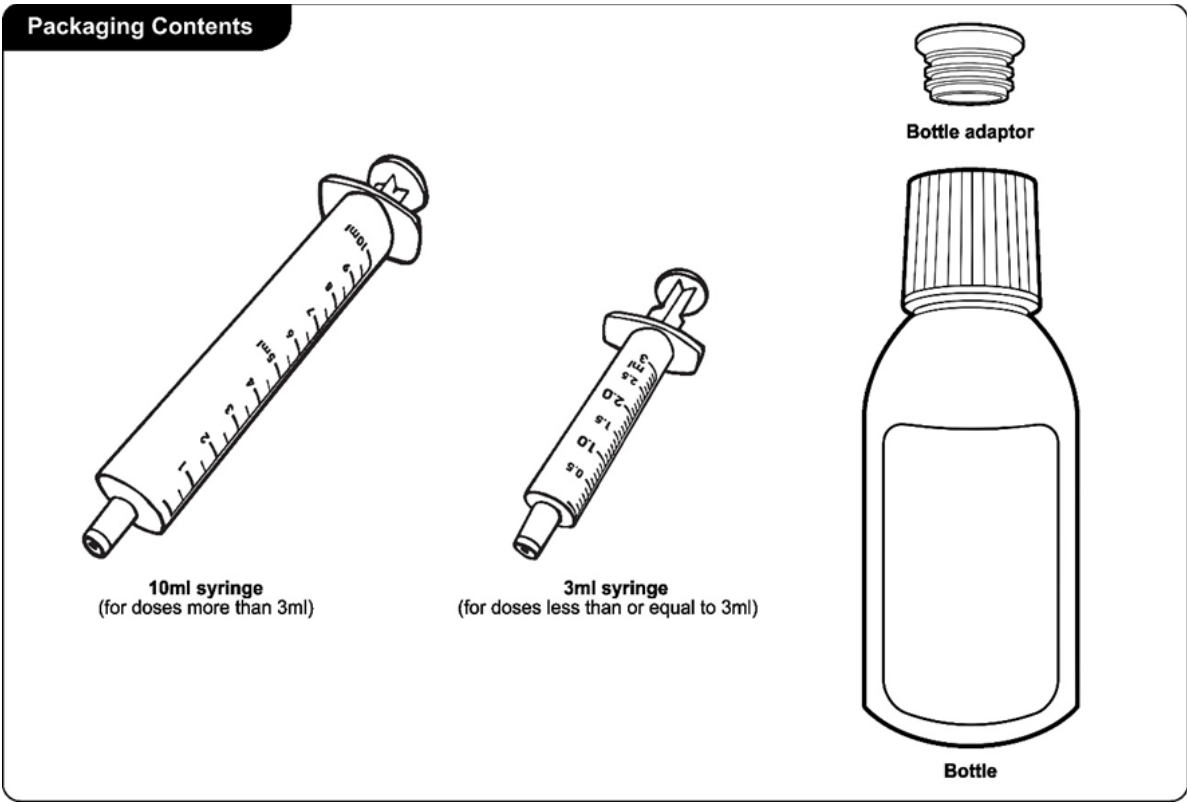
If you have kidney disease

Your doctor may need to give you a lower dose.

You should not take Xromi if you have severe kidney disease.

Handling

Your pack of Xromi contains a bottle of medicine, a cap, a bottle adaptor and two dosing syringes (a 3 ml and a 10 ml syringe). Always use the syringes provided to take your medicine.



It is important that you use the correct dosing syringe for your medicine. Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed.

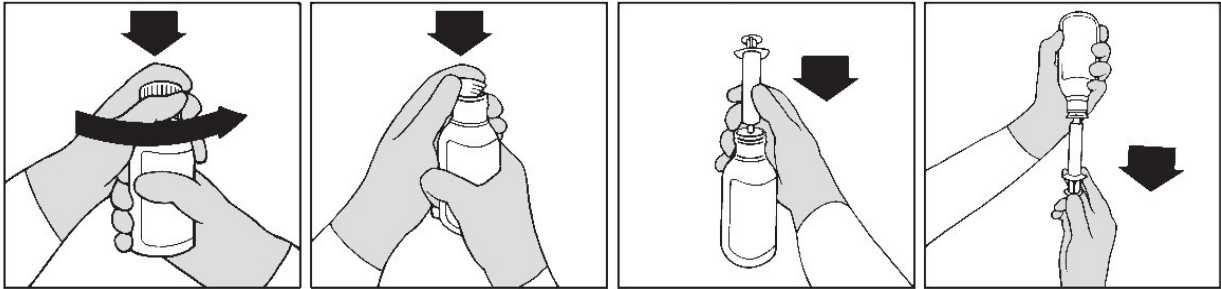
The smaller 3 ml syringe, marked from 0.5 ml to 3 ml, is for measuring doses of less than or equal to 3 ml. You should use this one if the total amount you have to take is less than or equal to 3 ml (each graduation of 0.1 ml contains 10 mg of hydroxycarbamide).

The larger 10 ml syringe, marked from 1 ml to 10 ml, is for measuring doses of more than 3 ml. You should use this one if the total amount you have to take is more than 3 ml (each graduation of 0.5 ml contains 50 mg of hydroxycarbamide).

If you are a parent or care giver administering the medicine, wash your hands before and after administering a dose. Wipe up spillages immediately. To decrease the risk of exposure disposable gloves should be used when handling Xromi. To minimise air bubbles, do not shake the bottle before administering a dose.

If Xromi comes into contact with skin, eyes or nose, it should be washed immediately and thoroughly with soap and water.

When you use the medicine follow the instructions below:



1. Put on disposable hand gloves before handling Xromi.
2. Remove the bottle cap (**figure 1**) and push the adaptor firmly into the top of the bottle and leave in place for future doses (**figure 2**).
3. Push the tip of the dosing syringe into the hole in the adaptor (**figure 3**). **Your doctor or pharmacist will advise you of the correct syringe to use, either the 3 ml or the 10 ml syringe in order to give the correct dose.**
4. Turn the bottle upside down (**figure 4**).
5. 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 (**figure 4**). If you are not sure about how much medicine to draw into the syringe, always ask your doctor or nurse for advice.
6. 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.
7. Gently put the tip of the syringe into your mouth and to the inside of your cheek.
8. 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.
9. Remove the syringe from your mouth.
10. Swallow the dose of oral solution then drink some water, making sure no medicine is left in your mouth.
11. Put the cap back on the bottle with the adaptor left in place. Ensure that the cap is tightly closed.
12. 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 that syringe again for dosing. Store the syringe in a hygienic place with the medicine.

Repeat the above for each dose as instructed by your doctor or pharmacist.

If you take more Xromi than you should

If you take more Xromi than you should, tell your doctor or go to a hospital immediately. Take the medicine pack and this leaflet with you. The most common symptoms of overdose with Xromi are:

- Redness of the skin,
- Soreness (touch is painful) and swelling of the palms of hands and soles of feet followed by the hands and feet becoming scaly,
- Skin becoming strongly pigmented (locally changes of colour),
- Soreness or swelling in the mouth.

If you forget to take Xromi

Tell your doctor. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Xromi

Do not stop taking your medicine unless advised by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following side effects, talk to your doctor or go to hospital immediately:

Very common: may affect more than 1 in 10 people

- A severe infection
- Fever or chills
- Tiredness and/or looking pale

Common: may affect up to 1 in 10 people

- Unexplained bruising (accumulation of blood under the skin) or bleeding
- Sore (open skin infection) on your skin

Uncommon: may affect up to 1 in 100 people

- Any yellowing of the whites of the eyes or skin (jaundice)

Rare: may affect up to 1 in 1000 people

- Ulcers or wounds on your legs

Very rare: may affect up to 1 in 10,000 people

- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints

Other side effects which are not mentioned above are listed below. Speak to your doctor if you are concerned by any of these side effects.

Very common: may affect more than 1 in 10 people

- Absence or low amount of sperm in the semen (azoospermia or oligospermia).

Common: may affect up to 1 in 10 people

- Nausea
- Headache
- Dizziness
- Constipation
- Darkening of the skin, nails and mouth
- Dry skin
- Hair loss

Uncommon: may affect up to 1 in 100 people

- Itching red eruption of the skin (rash)
- Diarrhoea
- Vomiting
- Inflammation or ulceration of the mouth
- Elevated liver enzymes

Other side effects (the frequency is unknown)

- Isolated cases of malignant disease of blood cells (leukaemia)
- Skin cancers in elderly patients
- Stomach pain or heartburn
- Gastrointestinal ulcer

- Fever
- Absence of menstrual cycles (amenorrhoea)
- Weight gain
- Low Vitamin D level in blood test
- Low magnesium level in blood test
- Bleeding

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Xromi

- Keep this medicine out of the sight and reach of children. Accidental ingestion can be lethal for children.
- Do not use this medicine after the expiry date which is stated on the carton and the bottle after 'EXP'. The expiry date refers to the last day of that month.
- After first opening of the bottle, discard any unused contents after 12 weeks.
- Store in a refrigerator (2 °C – 8 °C)
- Keep the bottle tightly closed to prevent spoilage of the medicine and reduce the risk of accidental spillage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xromi contains

The active substance is hydroxycarbamide. One ml of solution contains 100 mg of hydroxycarbamide.

The other ingredients are xanthan gum, sucralose (E955), strawberry flavour, methyl parahydroxybenzoate (E218), sodium hydroxide, and purified water. See section 2 "Xromi contains methyl parahydroxybenzoate".

What Xromi looks like and contents of the pack

Xromi is a clear, colourless to pale yellow, oral solution. It comes in glass bottles of 150 ml capped with a child-resistant closure. Each pack contains one bottle, a bottle adaptor and two dosing syringes (a syringe graduated to 3 ml and a syringe graduated to 10 ml).

Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed.

Marketing Authorisation Holder

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Manufacturer

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>