

CRYSVITA® (BUROSUMAB) INJECTION

Instructions for Use¹



Before you begin

Although you and your staff may be familiar with the preparation of drug suspensions and the administration of subcutaneous injections, it is important that you read all the instructions below for specifically administering CRYSVITA®. Please refer to the CRYSVITA® Australian Product Information for the recommended weight-based dose regimen. This dose is measured in millilitres (mL). Use the needle(s) indicated in the guidance below.

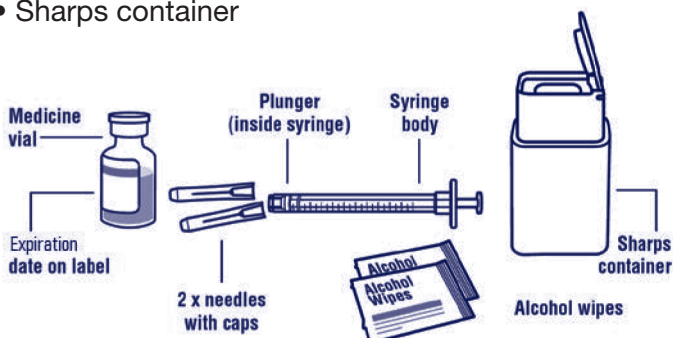
Important information

Before you use CRYSVITA®, read this important information:

- If, based on the dose regimen, you need to inject more than one vial of medicine, repeat Steps 2–4 in these Instructions for Use
- If you are giving the injection to a child, it may be helpful to have a colleague, parent or carer present to help you
- Always store the medicine vial in the refrigerator between 2°C and 8°C
- **DO NOT** expose the medicine vial to temperatures higher than 8°C or lower than 2°C
- **DO NOT** use any part that has missing pieces, appears to have been tampered with or is damaged or broken
- **DO NOT** freeze the medicine vials. Do not use a medicine vial that has been frozen
- **DO NOT** store the medicine vial in light
- **DO NOT** shake the medicine when it is in the medicine vial or the syringe. Shaking could cause the medicine to not work. If you shake the medicine, the solution in the vial or the syringe may look foamy and should not be used
- **DO NOT** reuse any opened medicine vials
- **ALWAYS** use one needle to draw medicine into the syringe and a **new** needle to administer CRYSVITA® to the patient

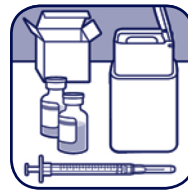
Please ensure the following supplies are available

- Medicine vial or vials
- Syringe(s) with plunger
- Needles (26 gauge recommended)
- Alcohol wipes
- Sharps container



For illustrative purposes only; an appropriate syringe and needle (26 gauge recommended) should be used

STEP 1:



Gather and inspect supplies

Remove the number of medicine vials you will need from the refrigerator. Place the medicine vial or vials and the additional supplies listed in the previous section on a clean, flat surface. If you are giving a second injection, you will need four needles, two syringes and two medicine vials for each patient. **DO NOT use the same needles or syringe for the second injection.**

DO NOT remove the needle cover until you are ready to inject.

Check the expiration date on the label of the medicine vial. **DO NOT** use a medicine vial if it is past the expiration date.

Inspect the medicine in the vial. **Only use the medicine if it is clear and colourless liquid and free of visible particles.**



Let the medicine vial warm to room temperature for **30 minutes**. **DO NOT** try to warm the medicine in any other way, such as with hot water or a microwave.



Wash your hands thoroughly with soap and water.

STEP 2:

You will repeat this step if you are giving a second injection



Remove the sealing cap from the medicine vial.



Clean the rubber stopper of the vial with an alcohol wipe. Be careful not to touch the rubber stopper after cleaning it.



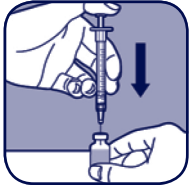
Remove the needle cover by pulling it straight off. **DO NOT** twist the needle cover. **DO NOT** touch the needle after the needle cover has been removed.



Pull back the plunger until it is even with the dose you have calculated using the CRYSVITA® Australian Product Information. This fills the syringe with air. **DO NOT** twist or bend the needle. **DO NOT** use the syringe if you drop it after removing the needle cap or if the needle appears damaged.



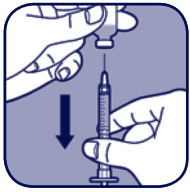
With the medicine vial right side up on the work surface, slowly insert the needle through the rubber stopper and into the medicine vial. **DO NOT** let the tip of the needle go into the medicine. If the needle does go into the medicine, withdraw the needle/syringe from the vial until the needle is no longer in the medicine before continuing.



Slowly push the plunger into the syringe. This pushes air from the syringe into the medicine vial. Doing this will help you draw the medicine into the syringe.



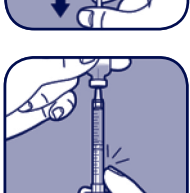
Turn the medicine vial, with the needle/syringe still in it, upside down.



Hold the medicine vial and needle/syringe straight up and down. Make sure the needle is in the medicine. This will help stop air bubbles from getting into the syringe.



Slowly pull the medicine into the syringe by pulling back the plunger until it is even with the dose you have calculated using the burosumab drug label information.



If there are no bubbles in the syringe, pull the needle out of the medicine vial. Be careful not to touch the needle. If you see bubbles in the syringe, lightly tap the syringe to bring the air bubbles to the top. Then gently push the plunger in slightly to push the air out of the syringe.



Make sure that the right amount of medicine is still in the syringe. If you need to add medicine, insert the needle/syringe into the medicine vial, turn it upside down, and pull back the plunger until you have the correct amount.

Put the needle cap on a clean, flat surface with something firm to 'push' the needle cap against. Insert the needle/syringe into the cap and push the capped needle against a firm object to fit the cap firmly onto the needle. Carefully remove the needle/cap from the syringe and replace it with a new, identical needle before moving to Step 3.

STEP 3:

You will repeat this step if you are giving a second injection



Prepare the injection site

Choose an injection site. You can use:

- Upper arm
- Buttocks
- Abdomen
- Thigh

DO NOT inject into an area that is tender, red, bruised, hard or has stretch marks.

If you are giving two injections, you must use two different injection sites.



Give the injections as soon after each other as possible. The maximum dosing volume per one (1) injection is 1.5mL.

Clean each injection site with a new alcohol wipe.

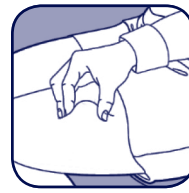
STEP 4:

You will repeat this step if you are giving a second injection

Inject

The injection site must be firm so that the needle goes into the fatty tissue.

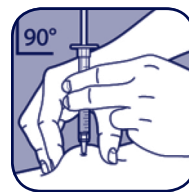
You can make the injection site firm by using the pinch method as shown:



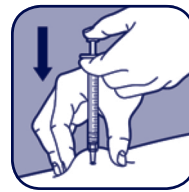
Pinch method

Pinch the skin firmly between your thumb and fingers, creating an area about 2 inches (5 centimetres) wide.

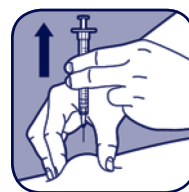
Hold the pinch throughout the injection.



Hold the syringe between your thumb and index finger. Use a quick 'dart-like' motion to insert the needle straight (90° angle) into the fatty tissue of the injection site. The entire needle should go all the way into the skin.



Push the plunger down until the syringe is empty.



After you have given the full dose, remove the needle by gently pulling the needle/syringe straight out of the injection site.

DO NOT recap the needle.

REMINDER: If you are giving a second injection, repeat Steps 2-4.

Use new needles, syringe and medicine vial. Choose a different injection site.

STEP 5:



Clean up

Immediately after the injection(s), put the used needle(s)/syringe(s) into a sharps container.

Any unused product or waste should be disposed of in accordance with local requirements.

PBS INFORMATION: This product is listed on the PBS as a Section 100 item.
Refer to PBS Schedule for full authority information.

Full PI Available at: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101> Last accessed September 2022.

Reference: 1. Australian Product Information for Crysvida® (burosumab) approved 10 September 2021. © All rights reserved. Kyowa Kirin Australia Pty Ltd, 68 York Street, Sydney, NSW 2000, Australia. www.kyowakirin.com/australia KKKAU-XLH-2209142. Date of preparation September 2022. Report adverse events to pv.kkau.2r@kyowakirin.com

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