

Beriner[®]

CSL Behring

Instructions

for subcutaneous injection of
Beriner[®] 2000 IU & 3000 IU

How to prepare and administer your Berinert® 2000 IU or 3000 IU by subcutaneous injection

This is your step-by-step guide to help you **prepare and administer your Berinert 2000 IU or 3000 IU as an injection under the skin** (known as a subcutaneous injection). This is different to administering Berinert 500 IU and 1500 IU as an injection into the vein (known as an intravenous injection), so you'll take different steps to prepare and administer it.

Remember, only self-administer your Berinert if you've been trained by your healthcare professional in how to do so — do not try to use this medicine without appropriate instruction.

If you're unsure about any of the steps in this guide, please talk to your healthcare professional.

When taking your Berinert, you should:

- always follow the specific instructions given by your healthcare professional and use your prescribed dose of subcutaneous Berinert
- remember to check the expiry date on the labels of the vials and do not use them after the expiry date
- always store the vials as indicated in the package leaflet

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple store.

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

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Berinert® is a registered trademark of CSL Behring

Mix2Vial® is a trademark of West Pharmaceutical Services, Inc. or a subsidiary thereof.

PART 1: Preparation



How to prepare your injection

Before you start:

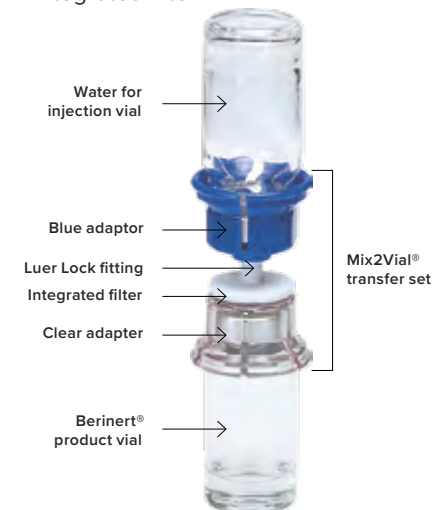
- Choose a hard, flat surface. Clean the surface carefully and set out all the items you'll need.
- Make sure the sterile water and product vial are at room temperature, and never use a cold solution. You can do this by leaving the vials at room temperature for about an hour (without opening them), or by holding them in your hands for a few minutes. Don't expose the vials to direct heat as they must not be heated above body temperature (37°C).
- Wash your hands thoroughly with warm water and soap.

You'll need the following items:


- Berinert® 2000/3000 IU product vial
- Water for injection vial
- Mix2Vial® transfer set
- Disposable syringe
- A subcutaneous needle, or a subcutaneous injection set with a tube (also called a butterfly)
- Plaster
- Alcohol swabs
- Sharps bin
- Your Berinert diary

Mix2Vial® – the needleless transfer system

- Reduced risk of needle stick injury during reconstitution
- Integrated filter

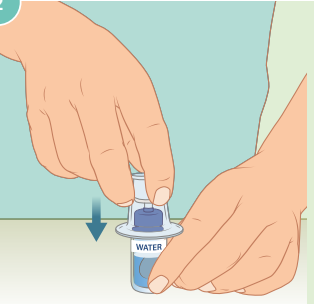


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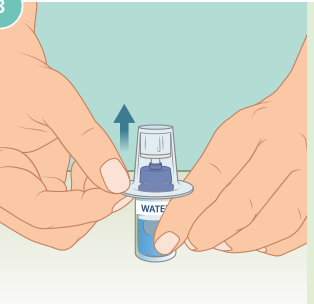
- Remove the protective caps from the water for injection vial and the product vial.
- Clean the exposed rubber stoppers of both vials with one alcohol swab each and let them dry.

2



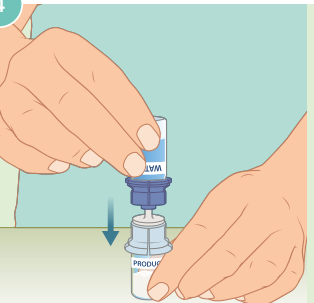
- Open the Mix2Vial® package by peeling off the lid. Do **not** remove the Mix2Vial® from the blister package.
- Place the water for injection vial on a clean, hard, flat surface and hold the vial tight.
- Take the Mix2Vial® together with the blister package and push the spike of the blue adapter end **straight down** through the water for injection vial stopper.

3



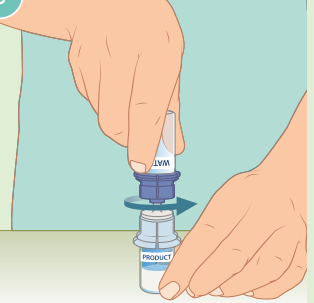
- Carefully remove the blister package from the Mix2Vial® set by holding at the rim, and pulling **straight upwards**.
- Make sure you only pull away the blister package and not the Mix2Vial® set.

4



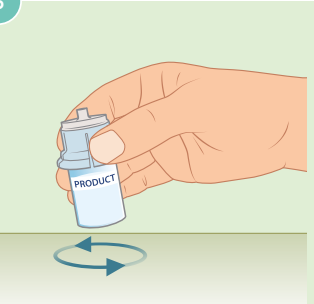
- Place the product vial on a clean, hard, flat surface.
- Turn the water for injection vial upside down with the Mix2Vial® set attached, and push the spike of the clear adapter end **straight down** through the product vial stopper.
- The water will automatically flow from the water for injection vial into the product vial.

5



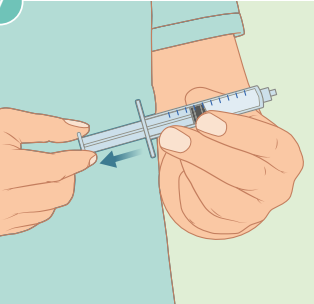
- Once the water for injection vial is empty, hold the product-vial side of the Mix2Vial® set in one hand. With the other hand, hold the water-vial side and unscrew the set carefully anticlockwise into two pieces.
- Discard the water for injection vial with the blue Mix2Vial® adapter attached. **Take care** not to touch the white contact point on the clear end.

6



- Gently swirl the product vial with the clear adapter attached until the powder is fully dissolved. Do not shake.
- Please note, the product for subcutaneous injection is highly concentrated and may take longer to completely dissolve than you're perhaps used to.

7



- Draw air into an empty, sterile syringe provided in the Berinert pack.

8



- While the product vial is upright, connect the syringe to the Mix2Vial's white fitting by screwing clockwise.

You should preferably use the solution straight away. If you don't administer the solution straight away, you must use it within 8 hours and only keep it stored in the vial.

PART 2: Administration

How to administer your subcutaneous injection

You can administer your Berinert subcutaneous injection in two ways:

- 1 Using a subcutaneous needle
- 2 Using a subcutaneous injection set with a tube (also called a butterfly)

You'll find instructions for each of these two methods in this guide. You can choose whichever works best for you.

Prepare your injection site

- Choose an area on your abdomen (stomach) for your injection, unless your healthcare professional has told you to use another area.
- Do not inject in the same place as your last injection. You should make sure you inject at least 5 centimetres away from the place where you gave yourself an injection before.
- Never give yourself an injection in areas where the skin is itchy, swollen, painful, bruised or red.
- Clean your skin at the injection site with an alcohol swab and allow the skin to dry for at least 30 seconds.

9

- Inject air into the product vial, but try not to inject any air into the solution, to avoid foaming.
- The slight overpressure in the product vial makes it easier to draw the solution into the syringe.

10

- While keeping the syringe plunger pressed, turn the system upside down and fill the syringe with the solution by pulling the plunger back slowly.

The solution should be colourless and clear to slightly opalescent (reflecting light). Do not use the solution if it is visibly cloudy or if it contains flakes or particles.

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- Once the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down).
- Disconnect the clear Mix2Vial® from the syringe by unscrewing anticlockwise.

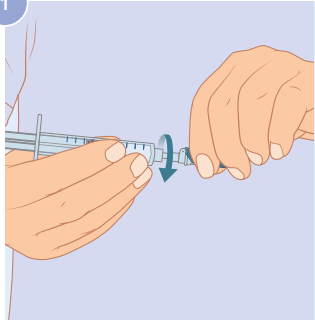
12

- Point the connection cone of the syringe upwards and expel the air from the syringe, being careful not to expel the solution.
- When putting down the syringe, make sure the syringe tip doesn't touch the surface.

If you need multiple vials for your dose of Berinert, use a separate, unused Mix2Vial® transfer set & one vial of sterile water for each additional vial of product, and repeat the previous steps.

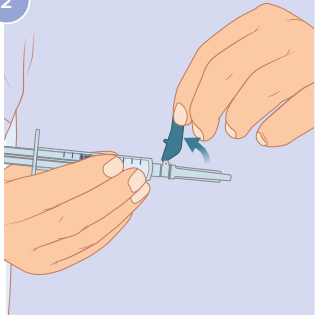
USING A SUBCUTANEEOUS NEEDLE

1



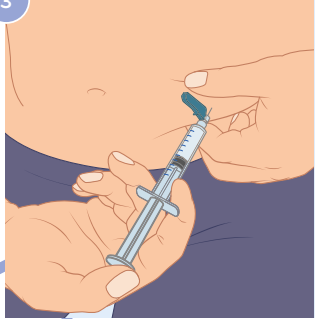
- Open the blister pack and secure the subcutaneous needle on the connection cone of the syringe with a slight twist, while holding it by the needle protection and cap.

2



- Pull back the needle protection and remove the needle cap.
- Gently press the syringe plunger to fill the needle with the solution as instructed by your healthcare professional.

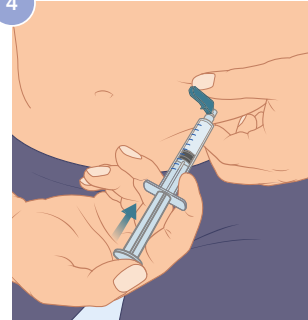
3



- Pinch a fold of skin with one hand
- Hold the syringe in your other hand between your fingers and the thumb
- Insert the needle under the skin at a 90° or 45° angle

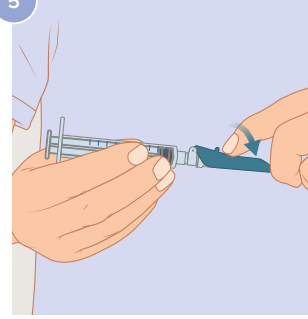
Make sure you don't inject the medication into a blood vessel. If you gently pull back the syringe plunger and see blood in the tube or syringe, change the needle. You don't need to replace the syringe with the medication.

4



- Slowly press the syringe plunger to inject the solution with the needle.
- You should inject the solution at a speed that feels comfortable for you. Your healthcare professional can help you with this.

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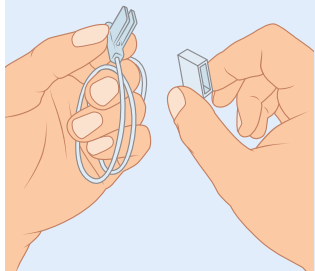


- Release the skin fold after administering all the medication.
- Carefully pull out the needle.
- Close the safety mechanism until it snaps over the needle.

- ▶ Dispose of unused medication & waste material in the sharps bin.
- ▶ Take off the label with the batch number from the product vial and stick it in your Berinert diary.
- ▶ Make a note of the date and time of the injection every time you use the medication.

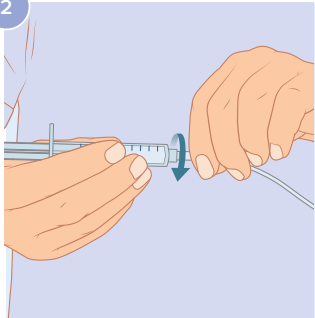
USING A BUTTERFLY

1



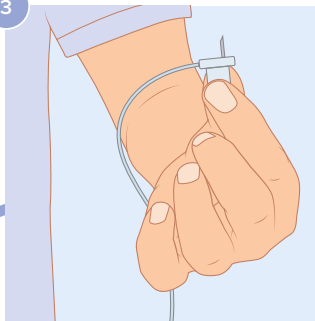
- Open the blister pack and remove a protective strip or clamp to spread the wings.
- Unwind the tube and unscrew the cap from the end of the tube.

2



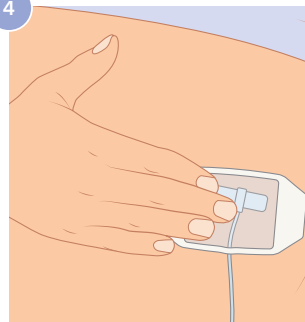
- Attach the end of the tube to the syringe cone with a twist so it clicks into place. Do not touch any of the connection points.
- Gently press the syringe plunger to fill the butterfly tube with the solution as instructed by your healthcare professional.

3



- Remove the cap from the needle without touching it.
- Bend the small wings over and hold them between your thumb and index finger.
- Insert the needle under the skin at a **90°** or **45°** angle.

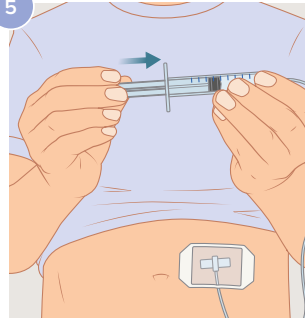
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- Secure the needle with the sterile plaster provided in the pack.

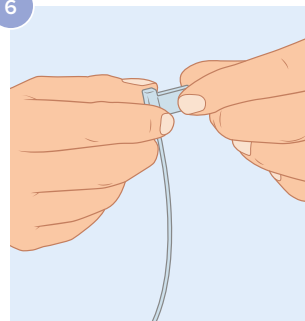
Make sure you don't inject the medication into a blood vessel. If you gently pull back the syringe plunger and see blood in the tube or syringe, change the needle. You don't need to replace the syringe with the medication.

5



- Slowly press the syringe plunger to inject the solution with the butterfly.
- You should inject the solution at a speed that feels comfortable for you. Your healthcare professional can help you with this.

6



- Carefully remove the plaster after administering all the medication.
- Pull the butterfly needle out of the injection site.
- Fold the two wings of the butterfly together to cover the needle.

- ▶ Dispose of unused medication & waste material in the sharps bin.
- ▶ Take off the label with the batch number from the product vial and stick it in your Berinert diary.
- ▶ Make a note of the date and time of the injection every time you use the medication.