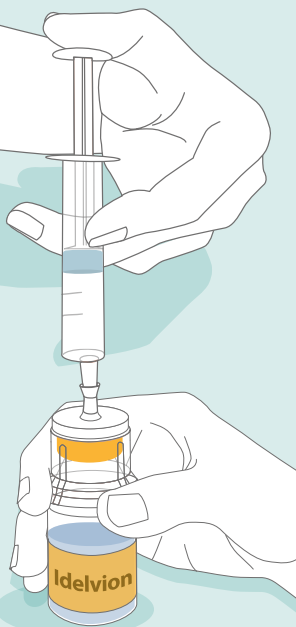


CSL Behring

Biotherapies for Life™

A guide
for parents*



Instructions for reconstituting and preparing Idelvion®

* This booklet has been designed for use **only by parents or carers of children who have been prescribed Idelvion.**

An Idelvion package leaflet can be found inside the Idelvion pack. Please read the complete leaflet carefully.

Idelvion®

albutrepenocog alfa
(Recombinant Coagulation Factor IX, Albumin Fusion Protein)

Getting started

As a parent you will want to make the routine of reconstituting and preparing your child's haemophilia B treatment as straightforward as possible. This step-by-step guide has been designed to help you.

Contact your child's haemophilia care team for further guidance if your child has a port.

Set out all the items you will need and prepare everything together on a clean, hard, flat surface, e.g. on an infusion mat.

Items for use during reconstitution included in each pack of Idelvion:

- **Idelvion product vial (vial containing powder)**
Do not use after expiry date
- **Water for injection vial (vial containing liquid)**
Do not use after expiry date
- **Mix2Vial transfer set**
- **Disposable syringe**
- **Alcohol swabs**

You will also find included in each pack of Idelvion:

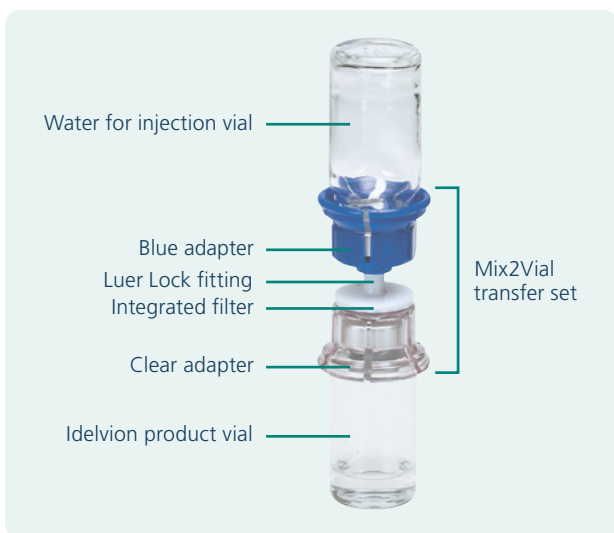
- **Venipuncture set (including butterfly needle)**
- **A plaster**

Contact your child's haemophilia care team if you are unsure about anything.

Your child's Mix2Vial®

Mix2Vial® – the needleless transfer system

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

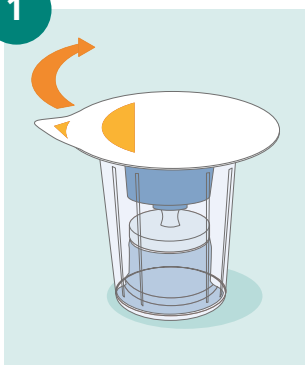


Before you start, disinfect the surface you will be working on. Wash your hands thoroughly, and make sure your child washes theirs too. Pay attention to cleanliness and do not touch the connection points of any of the equipment. Reconstitution and withdrawal must be carried out under sterile conditions.

How to help your child reconstitute Idelvion

Before you carry out the steps to reconstitute Idelvion, bring the water for injection vial and the product vial to room temperature (below 25°C). Remove the flip caps from both vials and wipe the rubber stoppers with a disinfecting swab. Allow to dry.

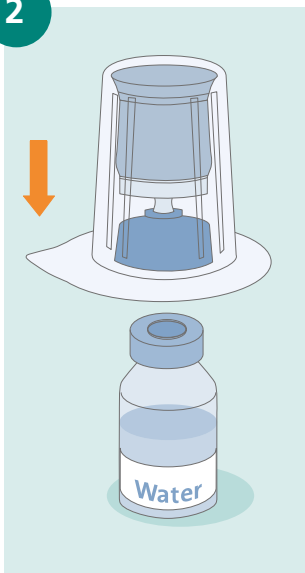
1



Open the Mix2Vial package by peeling off the lid.

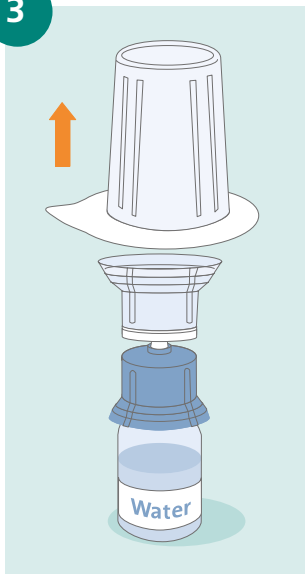
Do **not** remove the Mix2Vial from the blister package.

2



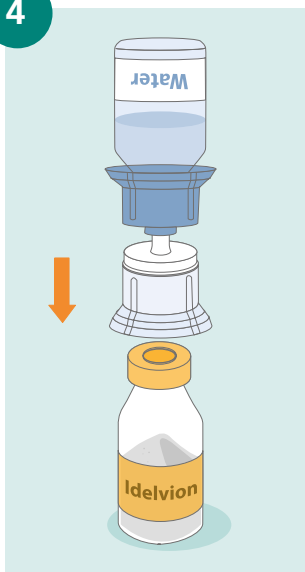
Place the water for injection vial on a clean, hard, flat surface and hold the vial tight. Take the Mix2Vial together with the blister package and push the spike of the blue adapter **straight down** through the water for injection vial stopper. The blue adapter locks onto the water for injection vial.

3



Hold onto the water for injection vial and carefully remove the blister package from the Mix2Vial by holding at the rim, and pulling **straight upwards** (do not tilt). Make sure you only pull away the blister package and not the Mix2Vial.

4

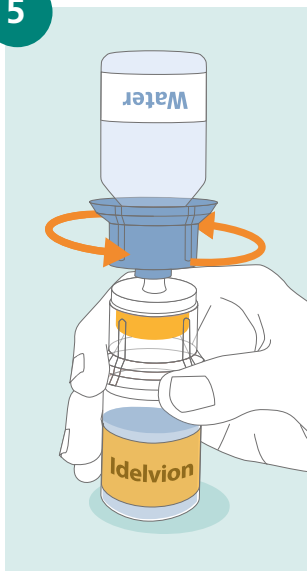


Place the product vial on a clean, hard, flat surface. Turn the water for injection vial upside down with the Mix2Vial attached, and push the spike of the clear adapter **straight down** through the product vial stopper. It is important that you do not lift the product vial off the flat surface.

The clear adapter locks onto the product vial. The water will automatically flow from the water for injection vial into the product vial.

How to help your child reconstitute Idelvion (cont.)

5



When the water for injection vial is empty, hold the clear adapter (product-vial side of the Mix2Vial) in one hand and the blue adapter (water-vial side) in the other. Carefully unscrew the Mix2Vial anticlockwise into two pieces.

6

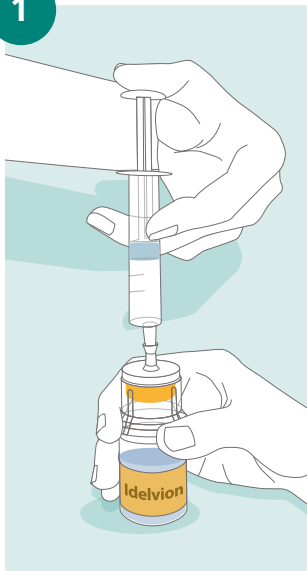


Discard the water for injection vial with the blue adapter attached.

Gently swirl the product vial with the clear adapter attached until the powder is fully dissolved. Take care not to touch the opening of the adapter, and do not shake.

How to help your child prepare Idelvion for injection

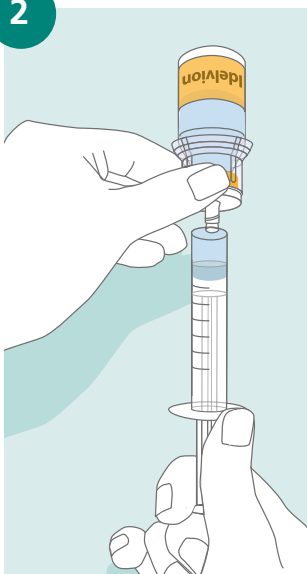
1



Draw air into an empty, sterile syringe (provided in the Idelvion pack). Keeping the product vial upright on a flat surface, connect the syringe to the Mix2Vial's Luer Lock fitting (the white fitting on the clear adapter) by screwing clockwise.

Inject air into the product vial, but try not to inject any air into the solution, to avoid foaming.

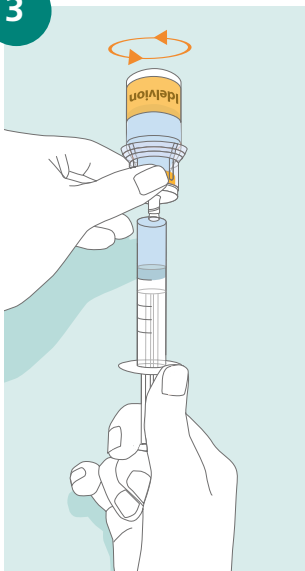
2



Turn the system upside down, keeping the plunger of the syringe pressed in. Fill the syringe with the solution by pulling the plunger back slowly.

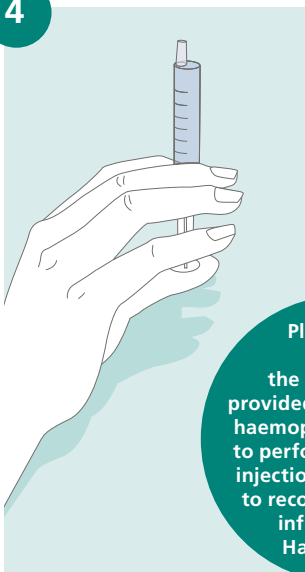
How to help your child prepare Idelvion for injection (cont.)

3



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

4



Point the connector tube of the syringe upwards and expel the air gently from the syringe, being careful not to expel the solution.

If you put the syringe down, make sure that the syringe tip does not touch any surface.

Please now follow the instructions provided by your child's haemophilia care team to perform your child's injection. Don't forget to record your child's infusion using Haemtrack.*

*Haemtrack is a secure website or phone app for recording the date and other details of your infusion, including the batch number(s), which can be found on the Idelvion box.

Frequently Asked Questions

Q What is the normal appearance of Idelvion?

A Idelvion is a pale yellow to white powder. The reconstituted solution should be clear or slightly opalescent, yellow to colourless in appearance.

Q How do I store Idelvion?

A Idelvion does not need to be stored in a refrigerator. Idelvion can be stored at room temperature (2–25°C). Do not store above 25°C. Do not freeze. The vials should be kept in the outer carton in order to protect from light. The product should be used before the expiry date on the carton. After reconstitution, the product should be used immediately and not stored for future use.

Q How do I make sure I use the Mix2Vial correctly when reconstituting Idelvion?

A The transfer of the water depends on a vacuum sucking it into the Mix2Vial. This works when the spike breaks through the rubber seal. To get the best flow this needs to happen with a swift, straight puncturing motion.

The Mix2Vial should be attached to the Idelvion product vial or water for injection vial vertically and perpendicularly to the surface of the stopper (that is, straight down without tilting to either side). That's why it is important that the Idelvion product vial is placed on a hard, flat surface when reconstituting.

When you invert the Mix2Vial and water for injection vial to attach them to the Idelvion product vial, avoid making contact with or piercing the rubber. This movement can create a cut in the rubber stopper of the water for injection vial, which can cause a loss of vacuum and prevent the water from transferring automatically when the vials are all joined.

Partial vacuum loss can also happen if you hesitate when pushing the spike of the clear adapter straight down through the Idelvion product vial stopper. The clear adapter spike of the Mix2Vial has an opening that is longer than the thickness of the stopper. Therefore, if the spike is inserted too slowly, the opening can form a bridge between each side of the stopper and release the vacuum too soon.

Q What happens if the water does not transfer successfully?

A Idelvion should be reconstituted using the Mix2Vial as recommended in the package leaflet. Should the water not transfer properly despite correct usage of the Mix2Vial, do not attempt to use the Idelvion product vial for injection. Retain the vials and contact your haemophilia care team immediately for advice.

Q What happens if the powder does not dissolve fully?

A Idelvion should be reconstituted using the Mix2Vial as recommended in the package leaflet. **Do not use solutions that are cloudy or that contain flakes or particles.** Should the powder not dissolve properly then gently swirl the Idelvion product vial until the substance is fully dissolved. Do not shake. The reconstituted solution can now be withdrawn from the Idelvion product vial with the syringe, ready for administration. In the event that the powder does not dissolve properly despite correct usage of the Mix2Vial and despite gently swirling the Idelvion product vial, do not attempt to use the Idelvion product vial for injection. Retain the vials and contact your haemophilia care team immediately for advice.

Reporting 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:

<https://yellowcard.mhra.gov.uk>.

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

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