



**Flolan Solution****Instructions for use with a vial adaptor and ambulatory infusion pumps**

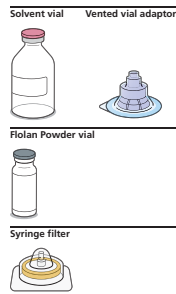
Please read these instructions before you start to prepare your Flolan solution, if you have any questions or concerns contact your Health Care Provider.

- Wash your hands thoroughly before you gather your supplies.
- Put on your gloves before (Step 1) 'Preparation' of Flolan.
- Keep your work area and your Flolan supplies clean and dry to make sure that you prepare Flolan in a sanitary way.
- Always follow your Health Care Provider's instructions exactly; the information in these instructions for use are intended to act as a reminder of the process.

**Storage information**

- Put out of the reach and sight of children.
- Store Flolan in a cool, dry place.
- Protect from light by keeping Flolan in its carton until it is used.

Do not use Flolan after the expiry date on the label. Do not freeze.

**Your pack will contain the following:**

- 1 x powder vial and, 1 solvent vial, and 1 vial adaptor and a filter unit;

OR

- 1 x powder vial, and 2 solvent vials, and 2 vial adaptors and a filter unit;

OR

- 1 powder vial.

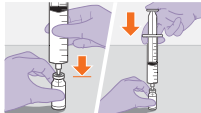
**You will also need (not supplied):**

- 1 x 60 mL syringe
- 1 x needle
- 1 x cassette
- 1 x ambulatory pump
- 1 x infusion set
- Gloves
- Alcohol wipes

**Making Flolan solution****7. Attach needle**

- Remove needle packaging.
- Attach the needle to the syringe.
- Remove the needle cap.

**Note:** Confirm that the needle is securely in place before removing the needle cap. Be careful not to touch the tip of the needle.

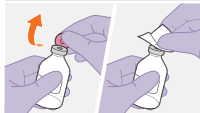
**8. Inject solution into Flolan powder vial**

- Remove the cap on Flolan powder vial and clean the rubber stopper by wiping it with an alcohol wipe.
- Insert the syringe needle vertically through the centre of the rubber stopper and inject the 10 mL of solvent into the vial containing the powder.

**9. Gently mix the solution**

- With the needle still inserted into the vial, gently shake the mixture until all of the powder has dissolved and the solution is clear.

**1. Do not use** if the solution has any color, or the powder has not completely dissolved.

**Preparation****1. Remove solvent vial cap**

Use only the solvent provided for reconstitution.

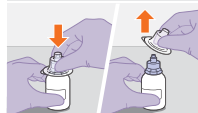
- Remove the cap on the solvent vial and clean the rubber stopper by wiping it with an alcohol wipe.

**2. Peel open vial adaptor packaging**

- Peel off the paper backing from the vial adaptor packaging.

**Note:** Keep the adaptor in place in its packaging for the next step.  
**Do not use** the vial adaptor if the packaging is damaged. Contact your doctor or pharmacist for further information.

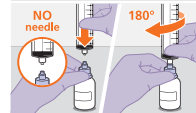
**Do not use** the vial adaptor if it falls out of the syringe.

**3. Attach vial adaptor**

- Hold the vial adaptor by the packaging and place the inner spike vertically into the rubber stopper on the solvent vial until the adaptor snaps into place.

Confirm that the adaptor is securely in place before removing the packaging.

Wipe the tip of the vial adaptor with an alcohol wipe.  
**Do not touch** the tip of the adaptor or the syringe.

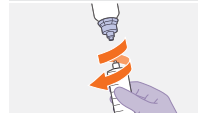
**4. Attach syringe without needle**

- Attach the syringe to the adaptor directly without using the needle.
- Hold the base of the adaptor while attaching the syringe.

Push and screw the syringe 180° clockwise onto the adaptor.  
**Do not attach** a needle to the syringe.

**5. Draw up solvent**

- Hold the vial securely above the syringe.
- Withdraw 10 mL of the sterile solvent solution into the syringe, through the vial adaptor.

**6. Unscrew syringe**

- Point the tip of the syringe up, and while gripping the bottom of the adaptor, remove the adaptor from the syringe. Screw the syringe counter clockwise to remove it from the vial adaptor.

**Note:** When preparing a solution, proceed to step 7. When directly injecting solvent, proceed to step 13.

**14. Gently mix cassette**

- Secure the slide clamp.
- Mix well, by rotating or swirling the cassette gently.

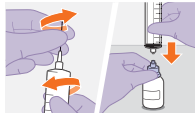
**Do not shake** the cassette.

**15. Ambulatory pump**

- Refer to instructions for using your ambulatory pump.

**10. Draw up prepared solution**

- When the solution is clear, turn the vial upside down, and with the syringe pointing up, draw up the Flolan solution into the syringe.
- Keep the needle below the surface of the solution to prevent air entering the syringe.
- Remove the needle from the vial.

**11. Inject solution into solvent**

- Remove the needle from the syringe and dispose in a sharps container.
- Reattach the syringe to the solvent vial's adaptor.
- Inject the Flolan solution into the remaining volume of solvent through the vial adaptor.

**Do not use** the needle together with the vial adaptor.

**Cassette preparation****\*Attach syringe filter**

- Note:** An in-line filter should be provided as part of your extension set, then the provided syringe filter must be used to filter the solution during preparation of the cassette.
- Attach the sterile syringe filter provided in your Flolan pack to the syringe.
- Attach the filter and syringe assembly to the cassette with the tube.

\*Orange steps are optional: only when required

**12. Mix thoroughly**

- Mix thoroughly. This solution is now referred to as the concentrated solution.
- Draw up the entire volume of concentrated solution from the vial.
- Disconnect the syringe from the vial adaptor as shown in Step 6.

**Note:** Only this concentrated solution is suitable for further dilution prior to use.

**13. Filling cassette**

- Attach the syringe to the cassette tube.
- Slowly inject the contents of the syringe into the cassette.
- Use the syringe to remove excess air from the cassette.

**Note:** Make sure that the slide clamp is open.

**\*Diluting solution**

- Note:** If your dose needs to be diluted, prepare additional solvent solution for injection by repeating steps 1 to 6 and 13. Follow the below instructions instead of step 5 for the volume of solvent to draw up.
- Hold the vial securely above the syringe.
- Draw up the required volume of solvent (or solution) from the vial.

**Disposal****Discard used supplies**

- Discard the sterile filter after you have finished preparing your Flolan solution, together with your other used supplies. You must also throw away any leftover pH 12 solvent, as it does not contain preservatives.

**Storage (Solutions with a concentration less than or equal to 150,000 ng/mL)****Storing the prepared solution**

- After you have finished preparing your Flolan solution you can use it at once or store it for up to eight days in a refrigerator at 2-8°C.
- The diluted solution should be protected from light. You should only store your Flolan solution after it has been fully diluted; the reconstituted solution should never be stored before it has been diluted.
- Store your Flolan cassettes at the top of the refrigerator in a box with a secure, closely fitting lid, and make sure they are kept separately from all food.
- Freshly prepared Flolan, or Flolan that has been refrigerated for up to eight days, can be used:
  - For up to 72 hours at up to 25°C
  - For up to 48 hours at up to 30°C
  - For up to 24 hours at up to 35°C
  - For up to 12 hours at up to 40°C
- Discard any unused solution after this time.