

How to minimise the risk of bloodstream infections with intravenous administration of Treposuvi[®]

Patient Brochure

The most important points

The purpose of this brochure is to reduce the risk of blood stream infections and sepsis that can occur with any long intravenous treatment, including intravenous treatment with Treposuvi.

Before you can use the infusion system at home, you will receive training from your clinical team to ensure that you can independently prepare and manage the administration of this medicine. This booklet is intended to support your training. Please take it home with you so that you can remind yourself of the most important points at any time. Keep it in a safe place. Your family members and/or carer may also want to read the booklet.

The first part of the booklet is an introduction to your medicine and the infusion system.

- Change your medication container and the infusion tube daily (every 24 hours).
- Replace your “split septum closed hub system” at least once every seven days.
- Change directly from the old to the new infusion system so that there is no interruption in the medication supply.
- Only stop the treatment if your doctor instructs you to.

The second part of the booklet provides instructions on how to keep the infusion system as clean as possible. If bacteria get into your bloodstream, you can get seriously ill.

- Check the place where the tube enters your body daily for signs of infection.
- Keep all system connectors dry, as water often contains bacteria.
- You should avoid submersing the infusion system in water. You should therefore not go swimming.
- You should change the wound dressing regularly and clean the skin often. If you use sterile, transparent wound dressings, change these at least every seven days. Change gauze wound dressings at least every two days.

You can ask your doctor or nurse at any time if there is anything you are unsure of. You should also read the Package Leaflet for further information about your medicine.

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1. Information about the medicine

Your medicine

Your medicine is called Treposuvi. You are receiving this medicine because your blood pressure is too high in the blood vessels between the heart and the lungs causing shortness of breath, dizziness, tiredness, fainting, palpitations or abnormal heartbeat, dry cough, chest pain and swollen ankles or legs. This is called “pulmonary arterial hypertension” or PAH.

Treposuvi is administered with a pump as a continuous infusion, which can be delivered intravenously (via a vein). It is infused directly and continuously into a large blood vessel via a central venous tube (catheter). The veins in the neck, groin or chest are most often used for this purpose.

Preparing your medicine

Your doctor will explain to you what dose you need and will explain to you in detail how to prepare your medicine before use. He will also make sure that you have correctly understood the steps necessary to prepare your medicine. If you have any questions, ask your doctor at any time.

Check the expiry date of all products you are using. Also, check that all liquids are clear and free from particles. The Treposuvi vial can be used for up to 30 days after first being opened.

The maximum duration of use of the diluted product should be no more than 24 hours.

- Use an alcohol swab to clean the rubber stopper on the vial.
- Carefully insert the needle into the rubber stopper at a 45-degree angle. Make sure that the bevelled edge of the needle points upwards.

- Place the needle at a 90-degree angle before inserting it fully into the rubber stopper. This prevents holes from forming in the rubber stopper over time. (These holes can let in bacteria from the air).
- Do not touch the connectors with your fingers when preparing the medication.
- When filling the pump that you are using, please adhere to the instructions for use for that respective pump and the corresponding container.

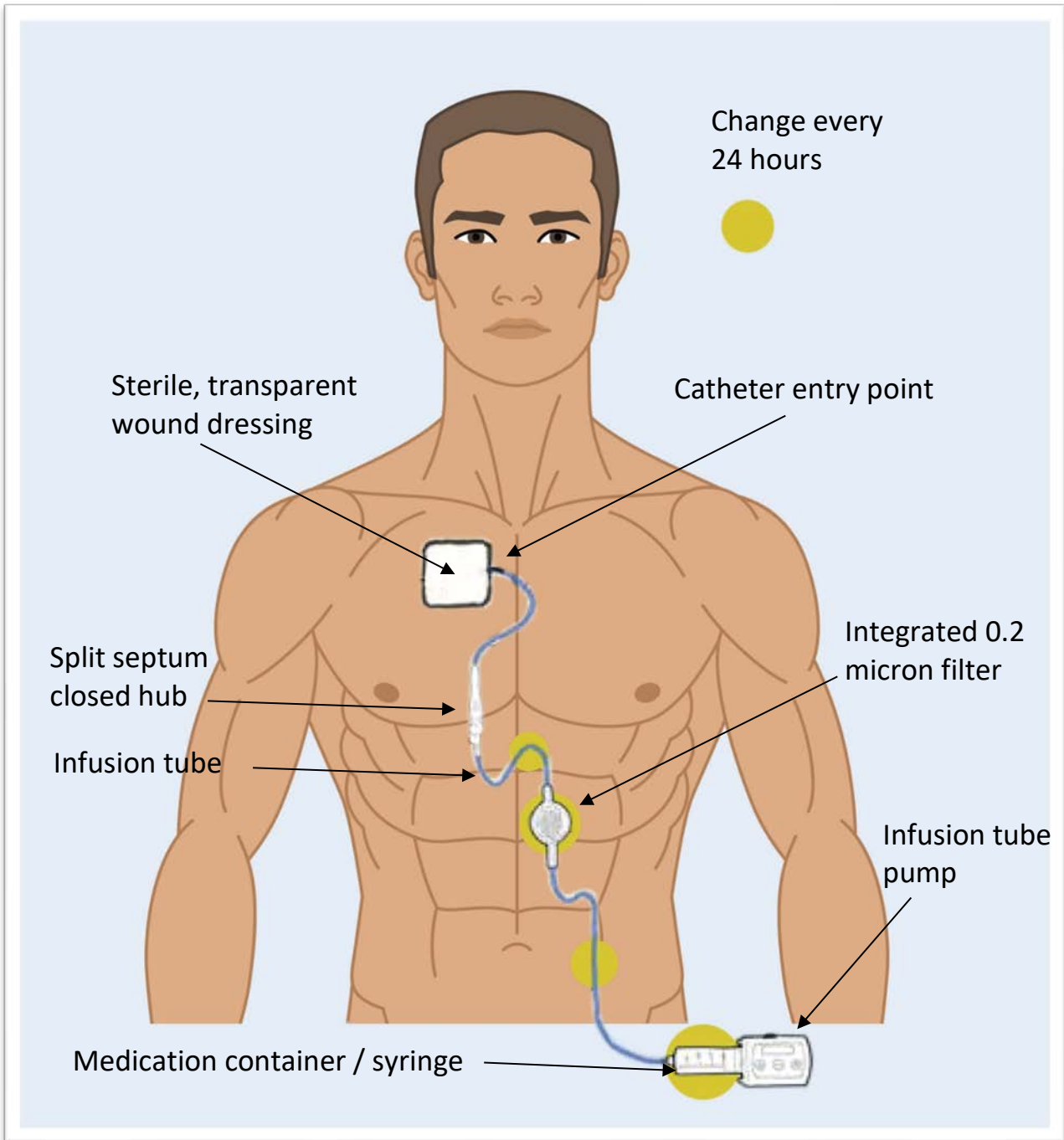
Choosing an infusion system

Your doctor will help you to choose the infusion system most suitable for you. Since you will potentially have to administer the medicine in this way for several months or years, you must be capable of using the device provided.

Before you can use it at home, you will receive training on how to use your infusion system to ensure that you can independently prepare and manage the administration of this medicine.

Ask your doctor or nurse at any time if there is anything you are unsure of.

Description of your infusion system



The image above shows an example of an infusion system. It depicts the infusion tube (catheter), which leads into a vein in the chest. This system uses a pump, a syringe containing the medication, infusion tubing and a split septum closed hub system with an in-line 0.2 micron filter. These components are explained in this booklet in more detail. Your infusion system may look differently depending on the pump and other accessories that you use.

Information about the infusion system

Your infusion system should be equipped with a closed hub device and an in-line 0.2 filter to help prevent bloodstream infections. The infusion system also includes a small pump that pumps the medicine into your body through a tube.

Information about the pumps

This pump runs in the background and delivers the medicine throughout the day.

- Your doctor will let you know how much medication you need. He or she will also tell you how to set the infusion speed on the pump.
- You will prepare enough of your medication for one day (24 hours) and place it in the appropriate container. You need to change your medication container and the infusion tube daily (every 24 hours).
- It must be prepared shortly before the 24 hours are up. You must change directly from the old to the new infusion system so that there is no interruption in the medication supply.

You can only use the medication container for 24 hours, even if there is still medication left. This is because the medication expires after 24 hours.

- The infusion line (tube) should only be disconnected from the closed hub device once every 24 hours at the time of replacement.

Use of closed hub systems

“Closed hub systems” work like a trap door. The use of a closed-hub system (preferably a split-septum) ensures that the lumen of the catheter is sealed each time the infusion system is disconnected and helps to reduce the risk of microbial contamination of the infusion system each time it is open.

- Use an alcohol swab to clean the closed hub device each time you remove the infusion tubing.
- The split-septum closed hub device should be replaced every 7 days.

Use of integrated 0.2 micron filters

Some tubes have a filter to eliminate bacteria that get into the system. If your tube does not already have a filter, an “integrated 0.2 micron” filter should be added to your system between the pump and the closed hub system.

- The filter should be replaced daily (every 24 hours) at the same time as the infusion tube and the medication container.

Integrated 0.2 micron filter



While using the infusion system

Do not stop using Treposuvi unless your doctor has advised you to. Abrupt withdrawal or sudden reductions in the dose may cause the pulmonary arterial hypertension to return with the potential for rapid and severe deterioration in your condition.

To ensure that your infusion system works without interruption, you should:

- Check your infusion tube daily to make sure that there are no kinks or loose connectors.
- Check whether the line clamp (if there is one) is open during administration.

You should always keep spare accessories in reserve: a backup pump, a medication container, an infusion tube and a split septum closed hub system, in the event that any of these fails unexpectedly.

Covering the tube insertion site on the body

Keep the skin surrounding the catheter insertion site covered with a dressing at all times. This keeps the area clean, dry and free from bacteria. Check your dressing daily. If your dressing is damp, loose or dirty, you should change it immediately.

There are two types of dressings that you can use:

- A “sterile transparent wound dressing” (change these at least every seven days).
- A “sterile gauze” wound dressing (change these at least every two day).

You can see through the “sterile transparent” wound dressing. This makes your daily inspections easier. If you have to pull up the edges of the wound dressing to have a look underneath, you should change the dressing.

2. How to prevent bloodstream infections

This section explains how you can prevent bloodstream infections, as if bacteria get into the bloodstream, you can get seriously ill.

- The most important thing is to keep your infusion system as clean as possible.
- As part of your training, you will learn how to set up your infusion system correctly.

Watch out for signs of an infection

Watch out for signs of an infection daily.

Should you notice one of the following possible signs of an infection, contact your doctor or nurse immediately:

- Red, warm or tender skin at the catheter insertion site
- Oozing or a bad smell at the catheter insertion site
- Fever, chills, generalised aches and pain (similar symptoms to the flu)
- General malaise (feeling of general discomfort, fatigue, or illness)

Topical antibiotic ointments or creams should not be applied as they may promote fungal infections and antimicrobial-resistant bacteria

Wash your hands

You must wash your hands thoroughly before preparing your infusion system each day.

First, you should take any jewellery off your wrists and hands.

- Use an antibacterial liquid soap. Do not use a solid bar of soap, as bacteria can grow on the surface of it.
- Use an alcohol gel if there is no antibacterial soap or clean, flowing water available.

Use the 6-step cleaning process explained here to do so:

1. Rub your palms together and massage the soap into your skin.



2. Place the right hand over the back of the left hand and rub between your fingers. Then swap and repeat this process with the left palm over the back of the right hand. Change back and forth to make sure that the soap penetrates your skin.



3. Press your palms together so that your fingers interlock. Rub them sideways.



4. Separate your fingers. Make a fist with your right hand and rub your closed fingers against your left palm. Then swap and repeat this process by making a fist with your left hand.



5. Mesh your thumbs together. Push your left thumb to rub against your right thumb. Then swap and repeat this process by rubbing your right thumb against your left one.



6. Place your right fingertips in your left palm. Rub against your palm in a circular motion. First clockwise, then anti-clockwise. Then swap and repeat this process with your left fingertips.



Use flowing water to rinse your hands from the wrist to the fingertips (for at least 20 seconds!). Never immerse your hands in standing water, as bacteria can grow in it. Use paper towels to dry your hands and to turn off the tap. Then throw the paper towels away.

Clean working area

Choose a place where no pets are kept, that is generally kept clean and where you will not be disturbed. Before you open any of the necessary items, you should clean the surface and the workstation thoroughly with an antibacterial/alcohol wipe.

Minimise exposure to water

Exposure of the infusion system to water can increase the risk of bacterial infection. It is therefore important to keep water away from the infusion system.

- At the time of replacing the split septum closed-hub system, there should not be any water visible in the luer lock connection threads. Do not disassemble your infusion system if one of the connectors is wet. Allow it to dry naturally.
- When washing, wrap a waterproof cover around the connectors (see image below). This stops the connectors from getting wet. Once you are finished and have dried yourself, remove the waterproof cover and discard it.
- Do not immerse the infusion system in water. Do not go swimming with it.
- Do not disconnect the infusion system to have a bath, shower or swim.



3. Summary reminder of timing of checks and equipment change

- Only use the medication container for 24 hours even if there is medication left as the medication expires after 24 hours
- Your medication can be used for up to 30 days after first being opened
- Prepare your medication and place it in a container that contains enough medication for one day (24 hours). Prepare the medication shortly before the 24 hours are up
- Change your medication container, the infusion tube and the integrated filter daily (every 24 hours)
- The infusion line (tube) should only be disconnected from the closed hub device once every 24 hours at the time of replacement
- Cover the skin at the catheter insertion (tube entry) site with a dressing at all times. Change your dressing if it is damp, loose or dirty immediately. Change the dressing at least every two days if you use a sterile gauze dressing, change it at least every seven days if you use a sterile transparent semi-permeable wound dressing
- Replace your closed catheter connector (split-septum closed hub device) at least once every seven days.

