

Use of an infusion system to administer Treprostinil Trepasuvi® into a vein

Patient information



The most important points

Due to the risk of central venous catheter-related blood stream infection the subcutaneous route is the preferred mode of delivery for treprostinil infusion therapy, and so continuous intravenous infusion should be reserved for those patients that are stabilised on a subcutaneous infusion and become intolerant of it and in whom the risks of an indwelling central venous catheter are considered acceptable.

This patient guide is a mandatory part of the approval of Treposuvi Solution For Infusion. This document is part of the additional risk-minimisation measures implemented to reduce the risk of occurrence of catheter-related blood stream infections when Treposuvi Solution For Infusion is administered by intravenous continuous infusion via an external infusion pump and a central venous catheter (CVC).

The other risk minimisation measures include a healthcare professional guide and a patient questionnaire. Copies of all these materials are available via the electronic Medicines Compendium (eMC) website, and patients should also read the patient information leaflet for this product via the electronic Medicines Compendium website: <https://www.medicines.org.uk/emc>

Before you can use the infusion system at home, you will receive training in how to use it. You must receive training until you feel confident using it. This booklet should help you during 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 or nursing staff may also want to read the booklet.

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

The second part of the booklet provides instructions for how to keep the infusion system as clean as possible. If bacteria get into the bloodstream, you can get seriously ill. A summary of the key points will be included at the end.

Once you start on this treatment, you will be asked by the clinical team responsible for your care to complete a short questionnaire after you have been on treatment for at least 3 months. The questionnaire will assess the ease with which you are able to apply the risk minimisation activities and identify any difficulties that you may experience. Completed questionnaires should be submitted to the clinical team responsible for your care.

You can ask your doctor or nurse at any time if there is anything you are unsure of or wish to know more about.

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1. Information about the medication

Your medication

Your medication is called Treposuvi. You are receiving this medication because you have high blood pressure in the blood vessels in your lungs. This is called “pulmonary arterial hypertension” or PAH.

When given intravenously, Treposuvi is infused directly into your deep, major veins via a tube. This tube is called a “central line”. The veins in the neck or chest are most often used for this purpose. This tube will make use of a cuffed and tunneled central venous catheter (CVC) with a minimum number of ports and will be inserted using sterile barrier techniques.

Treposuvi is administered using an “infusion system” that includes a pump device as well as the tubing and connectors. This booklet is part of a series of training documents explaining how to use the infusion system and explain the importance of proper hand hygiene and aseptic techniques when the catheter is inserted, replaced, accessed, repaired or when the catheter insertion site is examined and/or dressed.

Read the packaging insert in the Treposuvi box to find out more about your medication.

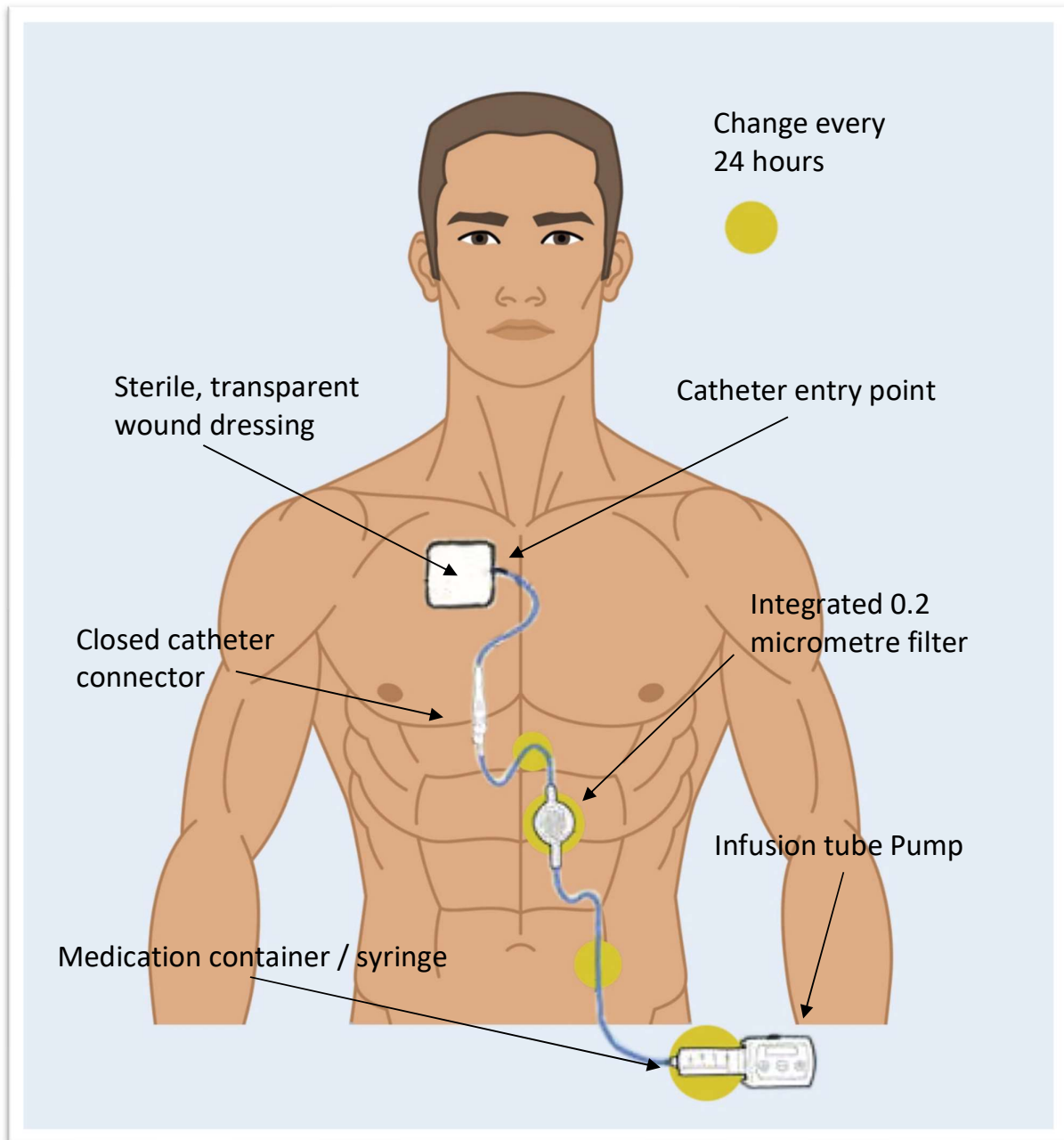
Choosing an infusion system

Your doctor will help you to choose the infusion system most suitable for you. Since you will potentially have to administer the medication 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 in how to use your infusion system. You must receive training until you feel confident using it.

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

How your infusion system looks



The image above shows an example of an infusion system. It depicts the infusion tube (central line), which leads into a large, deep vein in the chest. This system uses a pump, a syringe containing the medication and what is known as an integrated 0.2 micrometre filter. These components are explained in this booklet in more detail. Your infusion system may look different depending on the pump and other accessories that you use.

Information about the pump

The infusion system includes a small pump that pumps the medication into your body through a tube. This pump runs slowly in the background and inserts the medication into your body 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 prepare your medication and place it in a container that contains enough medication for one day (24 hours). You change your medication container and the infusion tube daily (every 24 hours).
- It must be prepared shortly before the 24 hours are up. 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 following example is of a typical pump that may be used:

Name:

CADD Legacy®

Where carried: In a pouch around the hips or over the shoulder

Size:

112 x 97 x 41 mm, weight around 391 g

Container:

Medication is administered from a 50-ml or 100-ml pouch.



While using the infusion system

Only stop the treatment if your doctor instructs you to, as you could otherwise suffer a setback. Should this occur, you may possibly feel unwell very quickly, out of breath and dizzy.

To guarantee 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 closed catheter connector, in the event that it fails unexpectedly.

2. This is how you prevent an infection from getting into your bloodstream

This section explains how you can prevent infections of the bloodstream in different ways, 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 in the right, i.e. “clean”, way.

Watch out for signs of an infection

Watch out for signs of an infection daily. If you have to pull up the edges of the wound dressing to have a look underneath, you should change the dressing.

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

- Red, warm or tender skin at the tube insertion site
- Oozing or a bad smell at the tube insertion site
- Fever, chills, pain (similar symptoms to the flu)
- General malaise

Wash your hands

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

First, you should take any jewellery off your wrist 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.



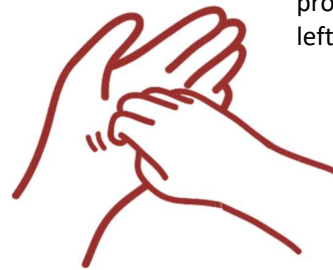
2. Place the right hand over the back of the left hand and rub between your fingers. Then swap and repeat this process with the left palm over the back of the right hand. Change back and forth to make sure that the soap penetrates your skin.



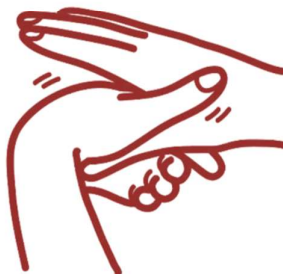
3. Press your palms together so that your fingers interlock. Rub them sideways.



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.

Ensure you have a 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 wipe.

Extracting and mixing your medication

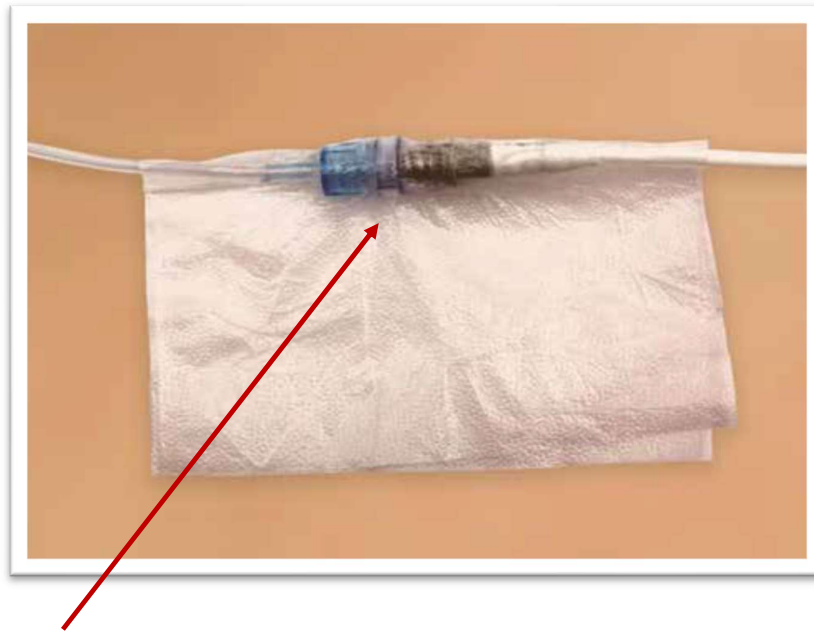
Check the expiry date of all products you are using. Also check that all fluids are clear and free from particles. The Treposuvi vial can be used for up to 30 days after first being opened.

- Use an alcohol swab to clean the rubber stopper on the vial.
- Insert the needle carefully into the rubber stopper at a 45-degree angle. Make sure that the bevelled edge of the needle points upwards.
- Insert the needle in the rubber stopper at a 90-degree angle before inserting it fully. This stops holes from developing 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.

Keep connectors dry

Water often contains bacteria. It is therefore important to keep your infusion system away from water.

- 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. This stops the connectors from getting wet. Once you are finished and have dried yourself, remove the watertight cover and discard it.
- Do not immerse the infusion system in water. You should therefore not go swimming.
- Do not take off the infusion system to have a bath, shower or swim.



Wrap a waterproof bandage around the connectors to keep them dry

Use of a closed-hub system

A “closed-hub system” works like a trapdoor. The use of a closed-hub system (preferably a split septum rather than a mechanical valve device), ensures that the lumen of the catheter is sealed each time the infusion system is disconnected. This reduces the risk of microbial contamination of the lumen. Use an alcohol swab to clean the connector when you remove the tube. Replace your closed catheter connector at least once every seven days.

The risk of contamination with water-borne Gram negative organisms is likely to be increased if a Luer lock inter-connection is wet at the time of exchanging either the infusion line or the closed hub. Therefore:

- swimming and submersion of the infusion system at the site of connection with the catheter hub should be discouraged
- at the time of replacing the closed-hub device, there should not be any water visible in the Luer lock connection threads
- the infusion line should only be disconnected from the closed hub device once every 24 hours at the time of replacement

Use of integrated 0.2 micrometre 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 micrometre” filter should be added to your system between the pump and the closed catheter connector. This is replaced daily (every 24 hours) at the same time as the infusion tube and the medication container.

Integrated 0.2 micrometre filter



Covering the tube insertion site on the body

Keep the skin surrounding tube where it enters the skin (tube entry site) covered with a dressing at all times. This keeps the area clean, dry and free from bacteria. Check your dressing daily. The dressing should be replaced whenever it becomes damp, loosened, or soiled or after examination of the site.

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 other day).

You can see through the “sterile transparent” wound dressing. This makes your daily inspections easier. If you prefer, you could also use a “sterile gauze” wound dressing.

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

How to report suspected problems and how to complete the patient questionnaire

If you have any questions or concerns while on this infusion treatment, please contact the clinical team responsible for your care.

There is a notes section at the end of this booklet for you to record the important contact information for your clinical team, home care provider and additional information about the infusion system settings you have been prescribed.

In addition, if you suspect you may have or have had a specific problem with the medication or its delivery system such 'adverse events' should be reported to the MHRA via the yellow card scheme at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to AOP Orphan Ltd., on 0121 262 4119 or drugsafety@pharsafer.com.

Once you start on this treatment, you will be asked by the clinical team responsible for your care to complete a short questionnaire after you have been on treatment for at least 3 months. The questionnaire will ask you a range of simple questions about your daily activities in managing the intravenous delivery system. Completed questionnaires should be submitted to the clinical team responsible for your care.

In summary

- Watch out for signs of an infection – these could be dangerous and must be prevented
- Wash your hands carefully using the 6-step cleaning process or as guided by your clinical team
- Ensure you have a clean working area in which to prepare and mix your medication
- In daily life, keep all connectors dry and make use of a closed-hub system to help avoid water contamination. The use of an integrated 0.2 micrometre filters also helps reduce the risks of contamination
- Pay attention to secure covering of the tube insertion site on the body and change dressings and connectors carefully at the recommended times

How to report suspected problems and how to complete the patient questionnaire

This booklet should help you with 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 or nursing staff may also want to read the booklet. You can ask your doctor or nurse at any time if there is anything you are unsure of.

This booklet is supplied to health service providers and patients by

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Additional Information

This page is for you and your clinical team to record key information about your care.

Details of your infusion therapy:

Points of contact for information and assistance:
