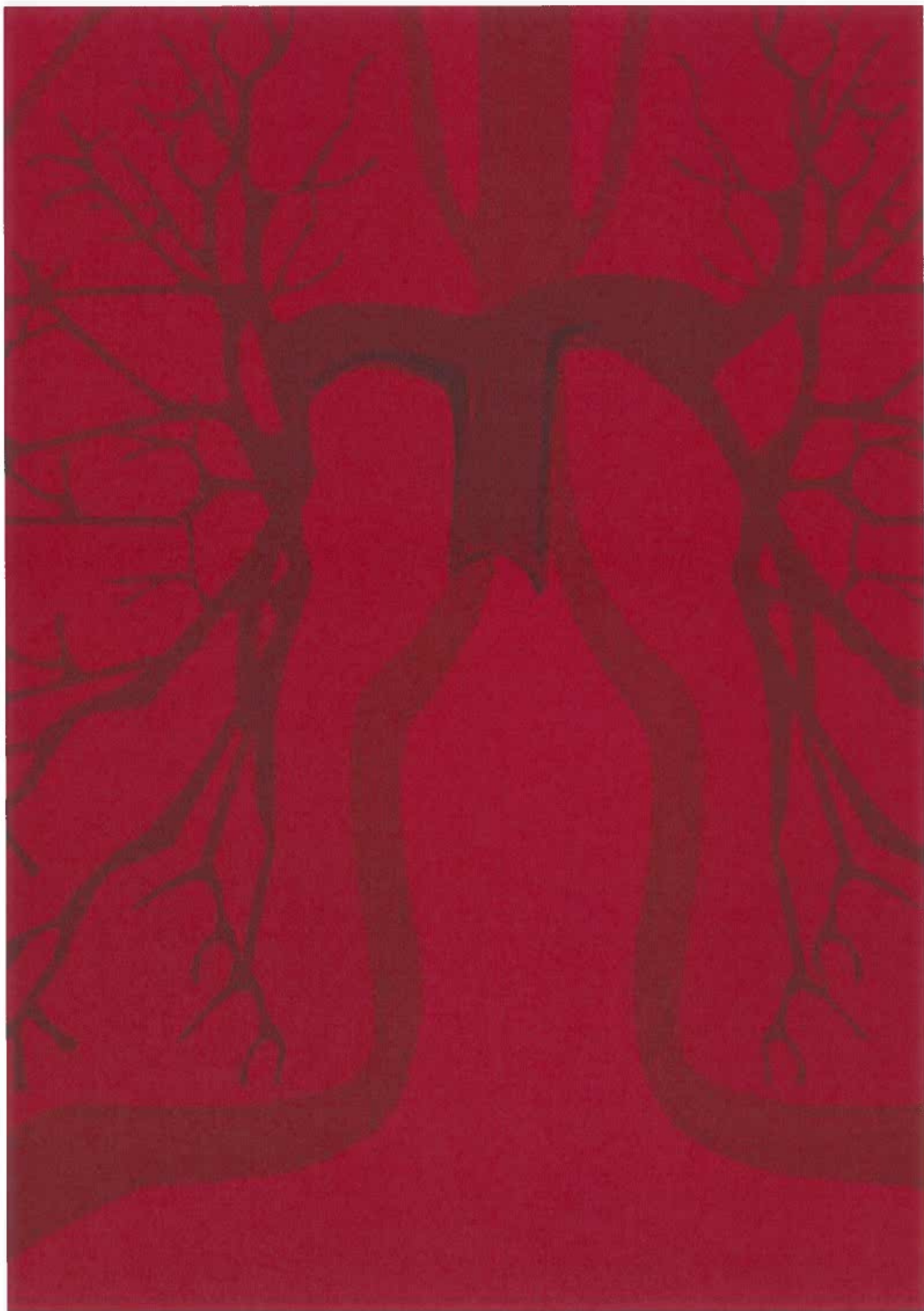


**Important safety
information:
Use of an infusion
system for intravenous
administration of
Remodulin® (treprostinil)**

Patient information





Introduction and Key Messages

This leaflet complements the instructions you will receive on how to use the infusion system at home until you feel comfortable doing so. Please take it with you to remember its main points and keep it in a safe place. You may also want your family or carer to read it.

The first part of this leaflet is an introduction to the medication and the infusion system. The following are the points to which you should pay particular attention:

- Change the medication reservoir and infusion tube every day (every 24 hours). Change your closed connector at least every 7 days.
- Switch immediately from your old infusion system to the new one, so that there are no breaks in the administration of the medication.
- Do not stop your medication unless you have been advised to do so by your doctor.

The second part of the leaflet explains how to keep the infusion system as clean as possible. This is very important, as you could become seriously ill if bacteria enter your bloodstream. The following are the points to which you should pay particular attention:

- Check daily for signs of infection at the site where the tube enters your body.
- Keep all system connections dry, as water sometimes contains bacteria.
- Do not place the infusion system in water or engage in activities, such as swimming, during which it could be under water.
- Change your bandages and clean your skin regularly. For sterilised transparent dressings, change every 7 days; for gauze dressings, at least every two days.
- If you have any questions, ask your doctor or nurse at any time.

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1. About the medication

The medication

You have been prescribed this medication (Remodulin) because you have high pressure in the blood vessels of your lungs: pulmonary arterial hypertension or PAH.

Remodulin is administered directly into one of your largest and deepest veins using a tube. This tube is called a central venous catheter (CVC). The most commonly used veins are in your neck or chest.

In order to enter your veins, the medication is administered via an "infusion system". This leaflet is part of a programme of instruction on how to use the infusion system.

Read the package leaflet inside the Remodulin pack to find out more about this medication.

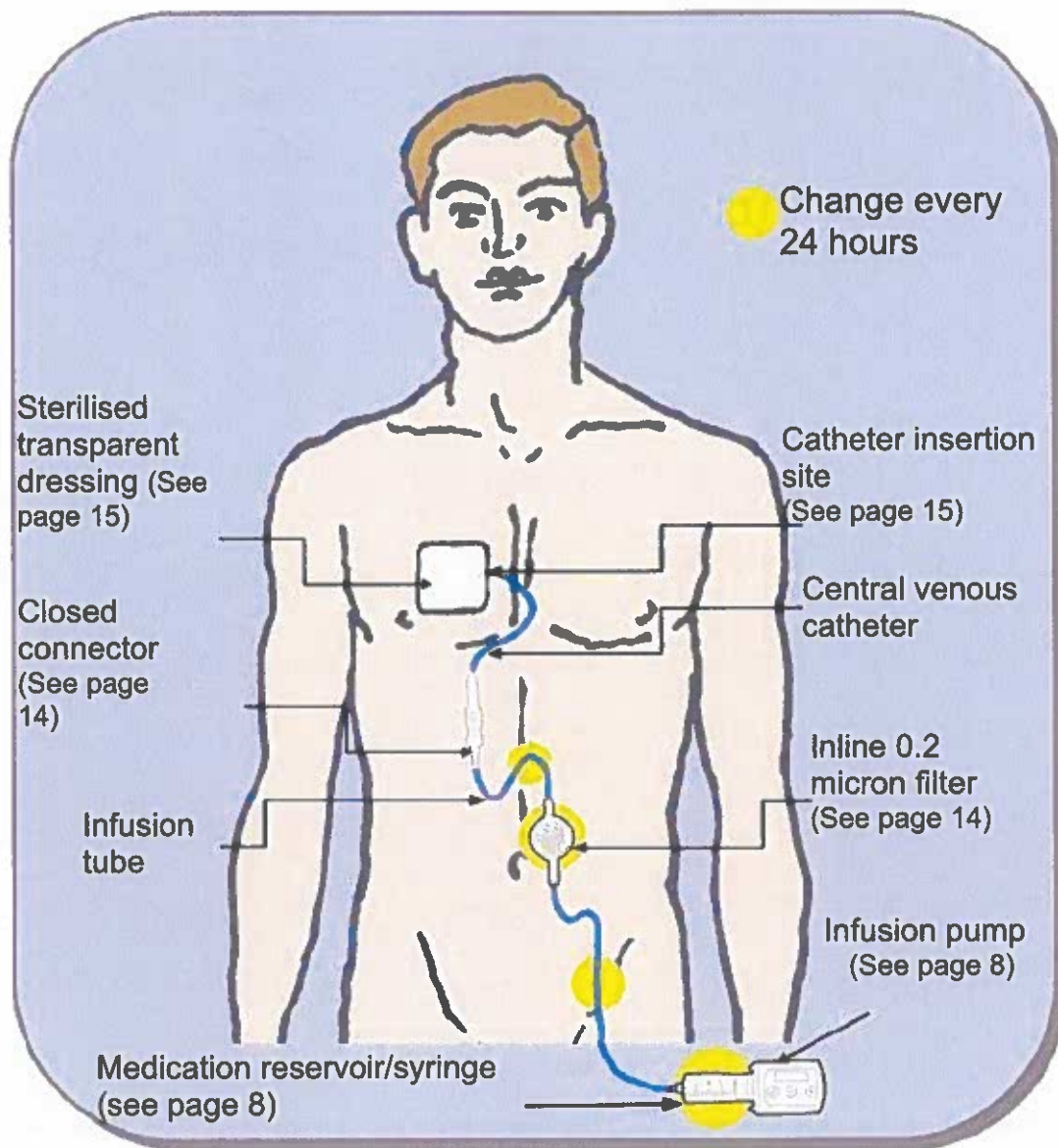
Choosing an infusion system

Your doctor will present you with alternatives for the types of infusion system, and the most suitable one will be chosen. You may have to receive the medication in this way for many months or years. It is therefore important that you are able to use the equipment provided.

You will be shown how to use the infusion system at home, which you will be able to do independently when you feel comfortable doing so.

If you have any questions, ask your doctor or nurse at any time.

Appearance of the infusion system



The figure above shows an example of an infusion system. It shows the infusion tube (central venous catheter) entering a large, deep vein in the chest. This system uses a pump, a syringe to contain the medication and an inline 0.2 micron filter. These will be explained later in this leaflet. The infusion system may look slightly different depending on the pump and other parts in use.

The infusion pump

The infusion system includes a small pump that pushes the medication into your body through the tube. This pump works silently, administering the medication 24 hours a day. Two different types of pump are shown below.

- Your doctor will tell you how much medication you need. They will also tell you how to set the infusion speed on your pump.
- You should prepare your medication and place it in a container that holds enough medication for one day (24 hours). You should change the medication reservoir and the infusion tube every day (every 24 hours).
- These should be prepared just before the end of the 24-hour period. Change the old infusion system for the new one immediately, so that there are no breaks in the administration of the medication.
- You should only use the medication container for 24 hours, even if there is still medication left over. This is due to the fact that the medication's shelf life is only 24 hours.

The two different types of pump are

Name: Syringe Pump

Mode of use: it is attached to a belt or around the neck in a small holder

Size: 77 x 47 x 29 mm weighing around 115 g

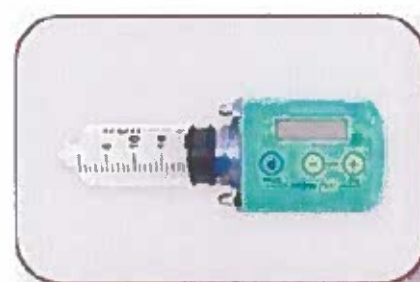
Reservoir: the medication is administered from a 20 ml syringe

Name: Ambulatory pump

Mode of use: in a bag around your waist or over your shoulder

Size: 112 x 97 x 41 mm weighing around 391 g

Reservoir: the medication is administered from a 50 or 100 ml cassette



Using the infusion system

Don't stop treatment unless you've been advised to do so by your doctor, as there could be a "rebound" effect which could make you feel suddenly unwell, dizzy and breathless.

To keep your infusion system running at all times:

- check the infusion tube every day to make sure there are no kinks or loose connections;
- check that the clamp on your catheter (if present) is open when in use.

It's also important to have a pump, a medication reservoir, an infusion tube and a closed connector in reserve, in case any of these stop working unexpectedly.

2. How to prevent a bloodstream infection

You can become seriously ill if bacteria enter your bloodstream. So to avoid it is very important:

- Keep your infusion system as clean as possible.
- Learn the correct "clean" way to use your infusion system

Identifying signs of infection

Check every day for signs of infection. If you have to lift the edges of the dressing to check underneath, change the dressing.

Speak to your doctor or nurse immediately if you notice any of the following possible signs of infection:

- red, hot or painful skin around the tube insertion site;
- liquid oozing or bad odour at the tube insertion site;
- fever, chills, body aches, like when you have flu;
- feeling ill generally.

Hand washing with the correct cleaning technique

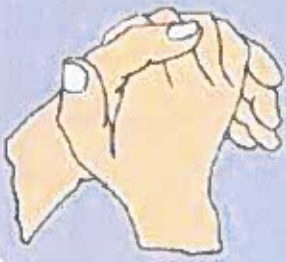
You should wash your hands thoroughly before preparing your infusion system every day.

First, remove all rings and bracelets.

- Use antibacterial liquid soap. Don't use bar soap, as it may have bacteria on the surface.
- Use alcohol gel if you don't have antibacterial liquid soap and clean running water.

The following steps will guide you through the correct hand washing technique:

- 1.** rub your hands palm to palm and massage the soap into your skin;



- 2.** place the palm of your right hand on the back of your left hand and rub between your fingers;



switch and do it again with your left hand on the back of your right hand; rub back and forth to make sure the soap covers all the skin;

- 3.** place your hands palm to palm again, but this time with your fingers crossed; rub from one side to the other;

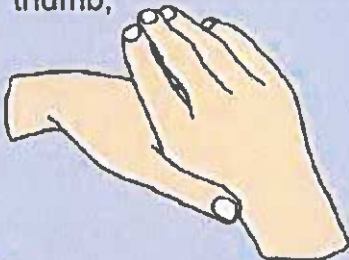


- 4.** separate your fingers; make a fist with your right hand and rub your folded fingers over the palm of your left hand;



change hands and repeat, making a fist with your left hand;

- 5.** cross your thumbs; rotate your left thumb to rub it against your right thumb; swap and do it again with the right thumb rubbing against the left thumb;



- 6.** place the tips of your right fingers in the palm of your left hand; rub the palm of your hand using circular movements;



do it clockwise and then anti-clockwise; change hands and repeat with the fingers of your left hand.

Use running water to wash your hands, from wrists to fingers, for at least 20 seconds; Never put your hands in standing water, as it may contain bacteria. Use paper towels both to dry your hands and to turn off the taps so you don't have to touch them again

once your hands have been washed. Discard the paper towels after using them only once.

Clean work area

Choose a place away from any household pets, generally clean and without distractions. Before opening any of the items you need, clean the work surface and preparation tray thoroughly with an antibacterial wipe.

Prepare and mix the medication

Check the expiry date of everything you use. Also check that all liquids are clear and free of particles. The Remodulin bottle can be used for up to 30 days after first use.

- Use some gauze impregnated with alcohol to clean the rubber cap of the bottle.
- Pierce the rubber cap slightly with the needle at a 45 degree angle. Make sure that the bevel (inclined tip) of the needle is facing upwards.
- Then place the needle at a 90-degree angle before pushing it all the way into the cap. This will prevent holes from forming in the rubber cover over time (holes that will let in airborne bacteria).
- Do not touch the connections with your fingers while preparing the medication.

Keep the connections dry

Water sometimes contains bacteria. This means that it is important to keep water away from your infusion system.

- Do not dismantle your infusion system if any of the connections are wet.
 - leave to dry naturally.
- Place a waterproof bandage around the connections while washing. This will prevent the connections from getting wet. When you have finished and it is dry, remove the waterproof dressing and discard it.
- Do not place the infusion system in water or engage in activities, such as swimming, during which it could be under water. You should not swim when receiving an IV infusion.



Putting a waterproof bandage on a connection to keep it dry.

Use of closed connectors

The closed connectors work like a trap door. This helps to reduce the number of times the infusion system is exposed to airborne bacteria. Use some alcohol-soaked gauze to clean the closed connector each time you remove the tube. Change your closed connector at least every 7 days.

Use of 0.2 micron filters

Some pipes have a filter to help remove any bacteria that enter the system. If the pipe does not already have a filter in it, a 0.2 micron filter should be placed in the system between the pump and the closed connector. This should be changed every day (every 24 hours) at the same time as the infusion tube and the medication reservoir.

0.2 micron filter



Protecting the tube insertion site

Keep the skin around the tube insertion site covered at all times using a dressing. This will keep the area clean, dry and bacteria-free. Check the dressing every day. If the dressing becomes damp, loose or dirty, change it immediately.

There are two types of dressing you can use:

- a sterilised transparent dressing (change at least every 7 days).
- a sterile gauze dressing (change at least every 2 days).

A transparent dressing allows you to see the skin and makes the daily checks easier. However, you can use a sterilised gauze dressing if you prefer.

If you have any questions, ask your doctor or nurse at any time.

This leaflet is provided to healthcare professionals and patients



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ADR Reporting

Suspected Adverse Drug Reactions or medication errors should be reported to the Malta Medicines Authority via the ADR reporting form, available online at <http://www.medicinesauthority.gov.mt/adrportal>.

The ADR reporting form can be sent by post to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or via email to postlicensing.medicinesauthority@gov.mt.

Alternatively, adverse drug reactions can also be reported to Central Procurement & Supplies Unit, (Head Office), UB002, Industrial Estate, San Gwann - SGN3000 or via email: info.cpsu@gov.mt.