Redunix

Treprostinil Sodium

50mg per 20ml (2.5mg/ml) / 100mg per 20ml (5mg/ml)

Patient Brochure

Administration of Treprostinil as intravenous infusion via an external pump and central venous catheter (CVC) (directly into a large vein)

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

This Patient Information is a mandatory part of the approval of Treprostinil Solution For Infusion. It has been assessed as an additional risk- minimisation measure to reduce the risk of occurrence of catheter-related blood stream infections upon administration by intravenous continuous infusion via an external infusion pump and a central venous catheter (CVC) and to increase the benefit-risk ratio.

Details of clinical team for patient reference

Responsible Consultant: _____

Hospital: _____

_____

Contact method to reach clinical team in case patient has issues or queries with treatment:

Telephone: _____

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Essential Points

Prostanoids such as treprostinil are powerful vasodilators (open up blood vessels) which allow more blood to flow through the narrowed blood vessels in the lungs in patients with Pulmonary Arterial Hypertension (PAH). Intravenous (IV) prostanoids are infused directly and continuously into a large blood vessel via a permanent catheter (a thin, flexible tube that is inserted into a vein). This catheter is called a Hickman line or a Groshong line. Prostanoids need to be infused continuously 24 hours a day because the body quickly breaks them down. You will need to carry your pump with you so it can drip the medicine through an indwelling central line into your body.

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. Continuous intravenous infusion is 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.

Before you can use the infusion system at home, you will receive training from your clinical team regarding its usage, which will allow you to feel confident about self-use of the therapy. You will be asked to complete a short questionnaire after initial education and after you have been on treatment for at least 3 months. The questionnaire will assess your knowledge of the measures to use your treatment safely as well as identify any particular difficulties that you experience taking your treatment that the clinical team responsible for your care can help address.

This brochure is intended to support you during your training. Please take it home with you so that you can always refer back to the essential points of your training. Keep it in a safe place. If necessary, your family members or nursing staff should also read the brochure.

The first part of the brochure gives an introduction to your medication and the infusion system. The first part of the brochure also contains instructions on the hygiene measures that you should adopt when preparing your medication and on keeping the infusion system and the catheter insertion site clean.

- You may become seriously ill if bacteria enter the blood stream.
- Change your drug container and infusion tube daily (every 24 hours). Replace your “closed hub connection" at least every 7 days (weekly).
- Change directly from the old to the new infusion system so that there is no interruption in the medication supply.
- Keep all system connections dry, since water often contains bacteria.
- Immersing the infusion system in water is not recommended. Do not swim with it.
- Change the dressing at the catheter insertion site regularly and clean the skin often. If you use sterile transparent dressings, change them at least every 7 days. Change gauze dressings at least every alternate day.
- Topical antibiotic ointments or creams should not be applied as they may promote fungal infections and antimicrobial-resistant bacteria.

The second part of the brochure provides instructions on the proper cleaning of your hands and work surfaces and on how to recognise signs of infection. If bacteria enter the blood stream, you may become seriously ill.

- Pay attention to hand and surface hygiene.
- Check the site where the tube enters your body daily for signs of infection.

Consult the clinical team responsible for your care in case of any doubts.

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1. Information on the medicinal product and the infusion system, including specific measures to prevent blood stream infections

Your Medicine

Your medicine is called Treprostinil Solution For Infusion (Treprostinil). You are taking this medicine because you have high blood pressure in the blood vessels of the lungs. This is called “pulmonary arterial hypertension" or PAH.

Treprostinil is administered via a tube directly into one of your large, deep veins. This tube is called a central venous catheter (CVC). The most commonly used veins are the cervical or thoracic veins.

To reach the veins, Treprostinil is administered with an “infusion system".

This brochure is part of training materials on the administration of Treprostinil as an intravenous infusion (directly into a vein) via an external pump and a CVC.

Read the package insert of Treprostinil Solution For Infusion carefully to understand more information about your medication.

Preparing your medicine

The clinical team responsible for your care will inform you about the dose that you need to take.

The clinical team responsible for your care will explain to you very precisely on how to prepare your medication before use. They will also check that you have understood the necessary steps to prepare your medication correctly. Consult your clinical team in case of any doubts.

For your reference when you are preparing your medication, your clinical team will legibly write down the amount of Treprostinil that you need to take from the vial with the strength indicated on the vial label. They will also write down the amount of the specified diluent that you need to mix with the amount of Treprostinil taken from the vial in order to achieve the necessary dilution.

Preparing your medicine

For the purpose of drug dilution, the clinical team can use the sheet below.

Important information on the dilution of Treprostinil for intravenous use (to be filled in by the responsible clinical team)

I. Take _____ millilitres (ml) from the Treprostinil vial of the following strength _____ milligrams per millilitre (mg/ml) as indicated on the vial label.

II. Diluent (cross out whichever is not applicable): Sterile water for injection or 0.9 % (w/v) sodium chloride for injection.

III. Please mix the amount of Treprostinil taken at step ***I***. with _____ _____ millilitres (ml) of the diluent specified at step ***II***.

Name of clinical team member: _____

Role: _____

Date: _____

Preparing your medicine

Please follow your clinical team's instructions very carefully on how to take Treprostinil, mix it and fill the drug container of your pump. Please consult with the clinical team in case of any doubts. For reference, always keep the above written instructions from the clinical team responsible for your care regarding the amounts to be used and the type of diluent handy.

When filling the pump that you are using, please adhere to the instructions for use for that respective pump and the corresponding drug container.

Always adhere to the following points when preparing your medication:

- Clean the work surfaces and your hands as described in the second chapter of this patient brochure (see page 12).
- Check the expiry date of all products you use. Also check that all liquids are clear and free of particles. The Treprostinil vial can be used for up to 30 days after the first use.
- Use an alcohol swab to clean the rubber stopper on the vial.
- Lightly prick the needle into the rubber stopper on the vial at a 45 degree angle. Ensure that the bevelled edge of the needle is facing upwards.
- Place the needle at a 90 degree angle before fully inserting it into the rubber stopper. This will prevent holes from forming in the rubber stopper over time. (These holes can let bacteria from the air into the vial)
- Do not touch the connections with your fingers while preparing the medication.

Your infusion system

Selecting an infusing system

Your clinical team will help you choose an infusion system that is best for you. Since you

may need to self-administer the medication using an infusion system for several months or years, you must be able to use the provided infusion system.

You will receive instructions on how to use your infusion system before it can be used at home. You will be instructed until you feel confident using the infusion system yourself.

Please consult your clinical team in case of any doubts. Your infusion system should be equipped with a closed lifting device and an in-line 0.2 filter to prevent bloodstream infections.

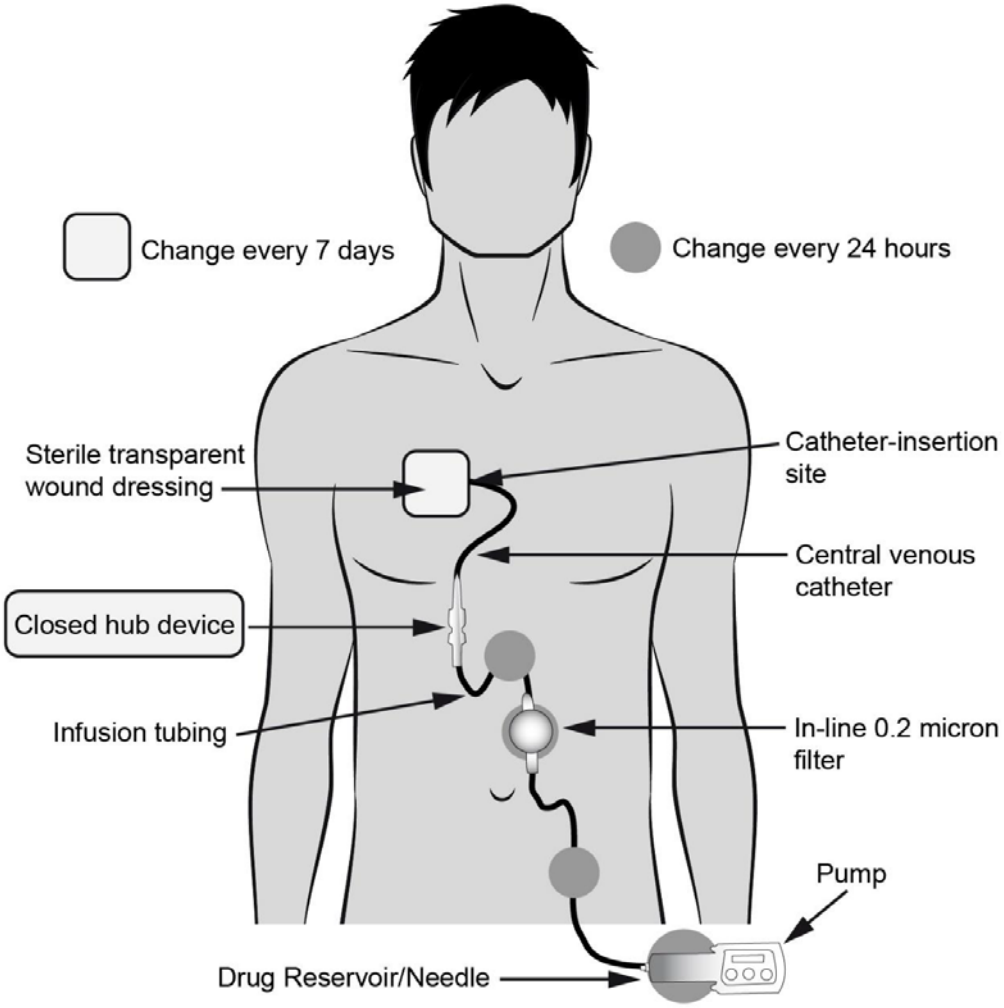
- Closed hub devices function like a trap door. They help in reducing how often your infusion system is opened for bacteria in the air.

Illustration of a closed lifting device
(Eg.: BD Q-SyteTM)

- An in-line 0.2 micron filter is supplied for eliminating bacteria that may enter the system. Some infusion systems contain an integrated filter. If your infusion system is not already equipped with a filter, an in-line 0.2 micron filter should be added between the pump and the closed lifting device.

Image of an in-line 0.2 micron filter
(Eg.: BD Medical MFX1823)

An infusion system looks like this



The above picture depicts an example of an infusion system. The central venous catheter that leads into a large, deep vein in the chest is shown. The central venous catheter is connected by a closed hub device to the infusion tube, which contains a 0.2 micron filter, and is connected to a portable pump. This infusion system is equipped with a pump that uses a syringe as the drug container. However, there are other types of pumps that use a bag as a drug container. Your infusion system may look different depending on the pump and other accessories you use.

Information regarding the pump

The infusion system includes a pump that delivers the medication directly and continuously into a large blood vessel via a permanent catheter (a thin, flexible tube that is inserted into a vein). The pump runs quietly in the background and delivers the medication to you throughout the day.

Your clinical team will explain the operation of the pump to you in greater details. They will also check that you have understood the working condition of the pump correctly. Please consult the clinical team in case of any doubts.

Your clinical team will inform what infusion rate is necessary for you. They will also explain how to set the infusion rate on the pump. Your clinical team will also write down the infusion rate you need to set on the pump for your future reference when preparing your treatment at home.

The clinical team can use the entry below for this purpose.

Important information regarding the infusion rate for intravenous use
(to be filled out by the clinical team)

Please set the infusion rate of _____ millilitres per hour (ml/h) on your pump.

Name of clinical team member: _____

Role: _____

Date: _____

You must replace the contents of your drug container and the infusion tube daily (every 24 hours). This is because the medication expires after 24 hours.

Please ensure you prepare your medicine shortly before the end of the 24-hour treatment period and place it in the drug container of your pump, as per the training you received from your clinical team.

Your clinical team will tell you exactly how to replace the drug container in your pump. This may vary depending on the pump type. If you are unsure, ask your clinical team at any time. Please also observe the instructions for use for the pump in question and the drug container that comes with it.

Changing the infusion system

Change your drug container and infusion tube daily. (Every 24 hours)

If your infusion system is not equipped with an existing filter, an in-line 0.2 micron filter should be added to your system between the pump and the closed hub device.

Replace your closed hub device at least every 7 days. Use an alcohol swab to clean the closed hub device each time you remove the infusion tubing.

Change directly from the old to the new infusion system so that there is no interruption in medication delivery.

Your clinical team will explain in detail how to change your infusion system. Please consult your clinical team in case of any doubts.

While using the infusion system

You may interrupt the treatment only as directed by your clinical team. Otherwise you could experience a “rebound effect”. If this occurs, you may feel unwell, out of breath and dizzy very quickly.

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

- Check your infusion tubing daily to ensure that there are no kinks or loose connections.
- Check that the catheter clamp (if present) is open during administration.
- In case of unexpected system failure, you should always have spare accessories available: a reserve pump, drug container, infusion tubing and a closed hub connection.

Keeping connections dry

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

- Do not disassemble your infusion system if any of the connections are wet. First allow these connections to air-dry naturally.
- Wrap a waterproof covering around the connections while showering.
- This will prevent the connections from getting wet. Once you have finished showering and have dried yourself, remove the waterproof covering and discard it.
- Do not immerse the infusion system in water. Do not swim with it.
- Do not disconnect the infusion system for bathing, showering or swimming.

Covering the catheter insertion site on your body

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

There are two types of dressing you can use:

- a “sterile transparent" dressing (change it at least every 7 days).
- a “sterile gauze" dressing (change it at least every other day).

The “sterile transparent" wound dressing is transparent. This can facilitate your daily dressing checks. However, if you prefer, you can instead use the “sterile gauze" dressing which is not transparent and must be changed at least every other day.

2.Signs of infection and general hygiene measures

This section explains how to detect signs of infection. It also explains the correct technique for cleaning hands and surfaces.

Watching for signs of infection

Watch for signs of infection every day. If you need to pull the edges of the dressing upwards to look underneath, you should change the dressing.

If you notice any of the following possible signs of infection, speak to your doctor immediately:

- Red, warm or tender skin at the catheter insertion site
- Oozing or a bad odour at the catheter insertion site
- Fever, chills, pain (similar to flu symptoms)
- 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.

Washing your hands

You must wash your hands thoroughly before the daily preparation of your infusion system. First of all, you should remove any jewellery from your wrist and hand.

- Use an antibacterial liquid soap. Do not use a solid soap bar since bacteria can grow on its surface.
- Use an alcohol gel if there is no liquid antibacterial soap and clean, running water.

Washing your hands

Use running water to rinse your hands from wrist to 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 turn off the taps. Then dispose the paper towels.

Clean work area

Choose a place where there are no pets, which is generally kept clean and where you will not be distracted. Before opening any of the required items, clean the surface and worktop thoroughly with an antibacterial wipe.

Reporting of side effects

If you notice any side effects, contact the clinical team responsible for your care. You can also report side effects directly to ***Sudair Pharma or Saudi Food and Drug Authority*** on the following website:
Sudair Pharma Company;
Email: pharmacovigilance@sudairpharma.com
Online: https://sudairpharma.com/report-a-side-effect/
Tel: 920001432 ext. 107
Mobile: 0546030507

Saudi Food and Drug Authority SFDA;
Email: npc.drug@sfda.gov.sa
online: https://ade.sfda.gov.sa
tel: 19999

By reporting adverse drug reactions, you can help to ensure that more information about the safety of this medicine is made available.

This brochure is intended to help you with your orientation. Please take it home with you so that you can always remember the essential points. Keep it in a safe place. If necessary, your family members or nursing staff should also read the brochure. ***Please consult your clinical team in case of any doubts***

Further information

For full information, please refer to the Summary of Product Characteristics (SmPC) for Solution For Infusion.

You will find the current SmPC and PIL on the Saudi Drug Information System (SDI) ***https://sdi.sfda.gov.sa/***

Additional information may be requested from Sudair Pharma Medical Team:

Email: ***medinfo@sudairpharrna.com.***

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