Redunix

Treprostinil Sodium

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

Questionnaire for patients

patients treated with intravenous Treprostinil via an external infusion pump and CVC

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

This Patient Questionnaire 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

Reason for completing questionnaire:

- ☐ Check patient knowledge after initial education
- ☐ Check patient knowledge after 3-6 months therapy
- ☐ Check patient knowledge after catheter-related blood stream infection*

** Report any suspected blood stream infections by e-mail to pharmacovigilance@sudairpharma.com*

Version: 1.0
Date: December.2022

Treating Physician:	Hospital:	
Date (questionnaire filled on):	Duration of the intravenous infusion therapy:	
Patient identification (according to entry in the patient file):	Patient age	Gender ☐ Male ☐ Female

Who filled out the questionnaire?
☐ Patient ☐ Medical professional (together with the patient)

Do you feel confident to perform your intravenous infusion treatment after the briefing?
☐ Yes ☐ No

How much time do you need to prepare for your treatment?
☐ less than 15 minutes ☐ 15 to 30 minutes ☐ 31 to 45 minutes
☐ 46 to 60 minutes ☐ more than one hour

Do you wash your hands with an antiseptic soap and clean your workspace with an antibacterial wipe before preparing your treatment?
☐ No ☐ Sometimes ☐ Often ☐ Always

What strength of Treprostinil in milligrams per milliliter (mg/ml) do you use? (Note: Information on the vial label)

What quantity of undiluted Treprostinil in millilitres (ml) do you take from the vial of the above mentioned strength?

Which diluent do you use?

With what quantity of the above diluent in millilitres (ml) do you mix the taken amount of undiluted Treprostinil?

What is the obtained total amount of diluted Treprostinil solution in millilitres (ml) when you have carried out all the necessary dilution steps?

Do you know how to fill the drug container of your pump with the diluted Treprostinil solution?
☐ Yes ☐ No

What is your current infusion rate in milliliters per hour (ml/h)?

How often do you change the drug container of your pump (bag or syringe)?

What type of central venous catheter (CVC) do you use?
☐ Hickman ☐ Broviac ☐ Groshong
☐ Other (please specify)

What type of dressing do you use at the catheter insertion site?
☐ Sterile gauze ☐ Transparent plastic bandage

How often do you change the dressing at the catheter insertion site?
☐ Every two days ☐ Weekly ☐ Every two weeks or less frequently

Does your infusion system already contain a filter?
☐ Yes ☐ No

If you answered with <No>: Do you install a separate filter when you change your infusion system?
☐ No ☐ Sometimes ☐ Often ☐ Always

Do you use a split septum closed hub device to connect the infusion system to your catheter?
☐ No ☐ Sometimes ☐ Often ☐ Always

How often do you change your infusion system?
☐ 24 hours ☐ 48 hours ☐ Other (Please specify)

How often do you change your closed hub device connection?
☐ 24 hours ☐ 48 hours ☐ Other (Please specify)

Do you use a waterproof dressing to keep the connection between your catheter and the infusion system dry when bathing/showering?
☐ No ☐ Sometimes ☐ Often ☐ Always

Do you know what action is to be taken if the connection between your catheter and the infusion system has become wet?
☐ Yes ☐ No

Describe the signs of infection that you should watch for daily:

Please return the completed questionnaire to the clinical team responsible for your care.

Review from responsible clinical team:
Date of review: _____
☐ Patient has demonstrated appropriate understanding/knowledge of their treatment
☐ Patient has NOT demonstrated appropriate understanding/knowledge of their treatment (please complete free text entry below)

Describe the gap in knowledge the patient demonstrated:

Has the patient been retrained to address the gap in knowledge demonstrated:
☐ Yes ☐ No

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

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.***