Patient Questionnaire

Questionnaire for patients treated with ***intravenous Treprostinil*** via an external infusion pump and central venous catheter (CVC)

This patient questionnaire is a mandatory part of the approval of Treprostinil Tillomed 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 Treprostinil Tillomed 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 brochure. Copies of all these materials are available via https://www.tillomed.de/index.html as well as on https://www.hpra.ie/homepage/medicines/safety-information/educational-material.

Prescribers and patients are asked to complete this short patient questionnaire which will help assess the ease with which patients are able to apply the risk minimisation activities and identify any particular difficulties that they experience which the clinical team can address.

Completed questionnaires should be sent via email to ***PVUK@tillomed.co.uk*** or via post at: 220 Butterfield, Great Marlings, Luton, LU2 8DL.

To be filled by the physician:

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 *PVUK@tillomed.co.uk***

Treating Physician:.....

Treatment Centre: .....

Date (questionnaire filled on): .....

Duration of the intravenous infusion therapy.....

Patient Initials: ..... Patient Identifier: .....

Patient Age:..... Patient Gender: ☐ male ☐ female

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

The following questions should be answered by the patient:
Return the completed questionnaire to the clinical team responsible for your care

1. **Do you feel confident in preparing and administering your intravenous infusion treatment after the education and training provided by your clinical team?**
   ☐ Yes ☐ No (speak to your clinical team to address any issues/concerns you have)

2. **Central venous catheter-related blood stream infections are a recognised risk of intravenous infusion treprostinil treatment**
   ☐ True ☐ False ☐ Do not know

3. **Prior to preparing your infusion or handling your infusion system/catheter do you wash your hands and follow aseptic techniques as advised by your clinical team?**
   ☐ No ☐ Sometimes ☐ Often ☐ Always

4. **Prior to preparing your infusion and replacing infusion system items (filters, hubs, tubing etc) do you check the expiry dates for the items and medication you will be using?**
   ☐ No ☐ Sometimes ☐ Often ☐ Always

5. **What strength of Treprostinil in milligrams per milliliter (mg/ml) do you use?**
   (Note: This information is on the vial label)
   .....

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

7. **Which diluent do you use?**
   ☐ Sterile water for injection ☐ 0.9 % (w/v) sodium chloride for injection
   ☐ Other (please specify).....

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

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

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

11. **What is the maximum duration of use of the diluted product that you prepare for infusion?**
    ☐ 24 hours ☐ 48 hours ☐ 72 hours

12. How often should you replace the contents of your drug container and the infusion tube?

☐ every 24 hours ☐ every 48 hours ☐ every 72 hours

13. How often should you replace the split-septum closed hub device of your infusion system?

☐ every 3 days ☐ every 5 days ☐ every 7 days

14. Does your infusion system already contain a filter?

☐ Yes ☐ No

15. If you answered "No" to Q14: Do you install a separate filter when you change your infusion system?

☐ No ☐ Sometime ☐ Often ☐ Always

16. What type of dressing do you use at the catheter insertion site?

☐ Sterile Gauze ☐ Sterile Transparent Dressing

17. How often do you change this dressing at the catheter insertion site?

☐ every 2 days ☐ every 7 days ☐ Other (please specify).....

18. If the dressing has become damp, loosened, or soiled or after examination of the catheter insertion site, what should be done?

☐ It should be washed with plain water
☐ It should be replaced
☐ Do not know

19. Do you go swimming?

☐ Yes ☐ No

20. Do you use a waterproof dressing to keep the connection between your catheter and the infusion system dry when bathing/showering?

☐ Yes ☐ No

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

.....

22. What should you do if you suspect infection associated with your catheter/treatment?

☐ Contact the clinical team/doctor immediately ☐ Do nothing

To be filled by the physician/clinical team responsible for the care of the patient:

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

Name of member of the clinical team reviewing this completed questionnaire:

Sign and date:

PLEASE SEND THE COMPLETED QUESTIONNAIRE TO ***PVUK@tillomed.co.uk*** OR TO 220 Butterfield, Great Marlings, Luton, LU2 8DL