Patient Questionnaire

This questionnaire is 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 Treposuvi Solution For Infusion (treprostinil sodium). 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 brochure. Copies of all these materials are available via the electronic Medicines Compendium (eMC) website - https://www.medicines.org.uk/emc/

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 AOP Orphan Ltd., at: drugsafety@pharsafer.com

<u>This section to be filled by the physician</u>

Treating Physician:	Treatment Centre:	
Date this questionnaire was completed on:	Duration of IV infusion treatment:	
Patient initials and unique identifier:	Age of the patient:	Sex of the patient: Male ☐ Female ☐

Form completed by:

Patient ☐ Specialist (with the patient) ☐

Reason for completing questionnaire:

☐ To check patient knowledge after initial education

☐ To check patient knowledge after 3-6 months therapy

☐ To check patient knowledge after catheter-related blood stream infection (In which case report any suspected blood stream infections by e-mail to drugsafety@pharsafer.com)

This section to be answered by the patient

1) Are central venous catheter-related blood stream infections a recognised risk of intravenous infusion treprostinil treatment?

Yes ☐ No ☐ Unsure ☐

2) Do you feel confident when administering the infusion treatment after the training?

Yes ☐ No ☐

3) How long does it take you to prepare your medication?

less than 15 min ☐ 15 – 30 min ☐ 31 – 45 min ☐ 46 – 60 min ☐ more than 1 hour ☐

4) Do you wash your hands with an antiseptic soap and clean your workspace with an antibacterial wipe before you prepare your medication?

Never ☐ Sometimes ☐ Often ☐ Always ☐

5) Do you use a waterproof dressing when bathing/showering to keep the connector between the catheter and the infusion tube dry?

Never ☐ Sometimes ☐ Often ☐ Always ☐

6) Do you go swimming?

Yes ☐ No ☐

7) Do you know what to do if your catheter connector gets wet?

Yes ☐ No ☐

8) What type of dressing do you use at the catheter access site on your body?

Sterile gauze dressing ☐ Transparent plastic dressing ☐

9) How often do you change the dressing at the catheter access?

Every two days ☐ Weekly ☐ Every two weeks or less often ☐

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

Wash it with sterile water ☐ Replace it ☐ Unsure ☐

11) What type of central line do you use?

Hickman ☐ Broviac ☐ Groshong ☐ Other (please specify) ☐ _____

12) Does your infusion tube already have a filter as part of the tubing?

Yes ☐ No ☐

13) If you answered <No>, do you attach a separate filter when you set up a new line?

Never ☐ Sometimes ☐ Often ☐ Always ☐

14) Do you use a split septum / closed hub catheter system to connect the infusion tube to your catheter?

Never ☐ Sometimes ☐ Often ☐ Always ☐

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

3 days ☐ 5 days ☐ 7 days ☐

16) 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?

Yes ☐ No ☐

17) What strength of Treprostinil in milligrams per millilitre (mg/ml) do you use? (See label on vial)

1mg/ml ☐ 2.5mg/ml ☐ 5mg/ml ☐ 10mg/ml ☐

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

_____

19) Which diluent do you use to make up your medication?

0.9% saline ☐ Sterline water ☐ Other (please specify) ☐ _____

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

_____

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

_____

22) What is the maximum duration of use of the diluted product that you prepare for infusion?

24 hours ☐ 48 hours ☐ Other (please specify) ☐ _____

23) What is your current medication flow rate in millilitres per hour (ml/hr)?

_____

24) What is the total volume of liquid that is filled into your reservoir (eg cassette or syringe)?

_____

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

26) What should you do if you suspect infection associated with your catheter/treatment?

Please return this form to your specialist PAH Team for them to send on to:

AOP Orphan Ltd
Colmore Plaza, 20 Colmore Circus Queensway
B4 6AT Birmingham, UK
Email: drugsafety@pharsafer.com

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 – if so, please 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 drugsafety@pharsafer.com

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

The current SmPC and PIL can be found on the eMC at www.medicines.org.uk/emc

Additional information may be requested from AOP Medical Information:
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