Summary of risk management plan for Treposa

This is a summary of the risk management plan (RMP) for Treposa. The RMP details important risks of Treposa, how these risks can be minimised, and how more information will be obtained about Treposa's risks and uncertainties (missing information).

Treposa's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Treposa should be used.

Important new concerns or changes to the current ones will be included in updates of Treposa's RMP.

I. The medicine and what it is used for

Treposa is authorised for the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of the disease in patients classified as New York Heart Association (NYHA) functional class III (see SmPC for the full indication). It contains treprostinil as the active substance and it is given by subcutaneous or intravenous infusion.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Treposa, together with measures to minimise such risks and the proposed studies for learning more about Treposa's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Treposa, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

If important information that may affect the safe use of Treposa is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Treposa are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be

regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Treposa. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	Risks attributable to Drug Delivery System: central venous catheter (CVC)-related bloodstream infections (BSIs) and sepsis (IV) Safety in patients with hepatic insufficiency Abrupt withdrawal or sudden large dose reduction Systemic hypotension
Important potential risks	Bleeding tendencies Co-administration with a CYP 2C8 inhibitor or inducer
Missing information	Safety of use in patients over the age of 65 years Safety of use in patients less than 18 years of age Safety of use in patients with renal dysfunction Effects of treprostinil infusion therapy on pregnancy, pregnancy outcome, labour and delivery, lactation

II.B Summary of important risks

Important identified risk: Risks attributable to Drug Delivery System: central venous catheter (CVC)-related bloodstream infections (BSIs) and sepsis (IV)	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.2, 4.4 and 4.8.* *PL section 2, 3 and 4* Routine risk minimisation activities recommending specific clinical measures to address the risk: *Advice on minimisation of the risk of CRBSIs in SmPC section 4.2* *Requirement of training for patients receiving a continuous IV infusion is mentioned in section 4.2 and mentioned in SmPC section 4.4* *Information on correct and hygienic handling of the infusion system in PIL section 3.* Other routine risk minimisation measures beyond the Product Information: *Prescription medicine only* Additional risk minimisation measures: *Healthcare professional letter / DDL (Dear Doctor*

Important identified risk: Risks attributable to Drug Delivery System: central venous catheter (CVC)-related bloodstream infections (BSIs) and sepsis (IV)	
	Letter) *Patient IV Information Brochure* *Patient Questionnaire* *HCP training slides*

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Treposa.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Treposa.