Summary of the risk management plan for Testosterone undecanoate Orifarm

This is a summary of the risk management plan (RMP) for Testosterone undecanoate Orifarm. The RMP details important risks of Testosterone undecanoate Orifarm, how these risks can be minimised, and how more information will be obtained about Testosterone undecanoate Orifarm risks and uncertainties (missing information).
Testosterone undecanoate Orifarm summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Testosterone undecanoate Orifarm should be used.

I. The medicine and what it is used for

Testosterone undecanoate Orifarm is authorised for testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests (see SmPC for the full indication).

It contains testosterone undecanoate as the active substance and it is given by an intramuscular injection.

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

Important risks of Testosterone undecanoate Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Testosterone undecanoate Orifarm 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 Testosterone Undecanoate Orifarm 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.

II.A List of important risks and missing information

Important risks of Testosterone undecanoate Orifarm 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 Testosterone undecanoate Orifarm. 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	– Pulmonary oil microembolism (POME)
Important potential risks	– Thromboembolic risk secondary to haematocrit increase
Missing information	– None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important identified risk: Pulmonary oil microembolism (POME)	
Risk minimisation measures:	Routine risk communication: SmPC • Sections 4.4, 4.8 PL • Sections 4, 6 Restricted medical prescription Additional risk minimisation measures: Educational brochure for health care professionals on the correct injection technique, recognition and management of POME.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None.

Important potential risk: Thromboembolic risk secondary to haematocrit increase

Risk minimisation measures:	Routine risk communication: SmPC • Sections 4.4, 4.8 PL • Sections 4, 6 Restricted medical prescription Additional risk minimisation measures: *None*.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None.

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 Testosterone undecanoate Orifarm.

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

There are no studies required for Testosterone undecanoate Orifarm.