PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR TESTOSTERONE ENANTATE DESMA 250 MG ML, SOLUTION FOR INJECTION

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

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

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

1. The medicine and what it is used for

Testosterone Enantate DESMA is authorised for Testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests. It contains Testosterone enantate as the active substance and it is given by intramuscular route.

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

Important risks of Testosterone Enantate DESMA, together with measures to minimise such risks and the proposed studies for learning more about Testosterone Enantate DESMA'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 Testosterone Enantate DESMA 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.

2.A List of important risks and missing information

Important risks of Testosterone Enantate DESMA 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 Enantate DESMA. 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

2.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 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 Sections 4, 6 Restricted medical prescription Additional risk minimisation measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None.

2.C Post-authorisation development plan

2.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 Enantate DESMA.

2.C.11 Other studies in post-authorisation development plan

There are no studies required for Testosterone Enantate DESMA.