

Part VI: Summary of the risk management plan

Summary of risk management plan for Testosterone 1000 mg/4ml solution for injection.

This is a summary of risk management plan for Testosterone 1000 mg/4ml solution for injection. The RMP details important risks of Testosterone 1000 mg/4ml solution for injection, how these risks can be minimised, and how more information will be obtained about Testosterone 1000 mg/4ml solution for injection, risks and uncertainties (missing information).

Testosterone 1000 mg/4ml solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Testosterone 1000 mg/4ml solution for injection should be used.

Important new concerns or changes to the current ones will be included in updates of Testosterone 1000 mg/4ml solution for injection 's RMP.

I. The medicine and what it is used for

Testosterone 1000 mg/4ml solution for injection is authorised for Testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests. It contains Testosterone undecanoate as the active substance and is to be given by intramuscular injection.

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

Important risks of Testosterone 1000 mg/4ml solution for injection, together with measures to minimise such 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 1000 mg/4ml solution for injection, these measures are supplemented with additional risk minimization 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 1000 mg/4ml solution for injection 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 1000 mg/4ml solution for injection. 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 Risk	Pulmonary oil microembolism (POME)
Important Potential Risk	Thromboembolic risk secondary to haematocrit increase
Missing information	None

II.B Summary of important risks

Important Identified Risk: Pulmonary oil microembolism (POME)

Risk minimisation measures	<p>Routine risk communication:</p> <ul style="list-style-type: none"> • SmPC sections 4.2, 4.4 and 4.8 <p>Routine risk communication recommending specific clinical measure to address the risk:</p> <ul style="list-style-type: none"> • Recommendations to monitor for symptoms during and immediately after each injection (to allow early recognition) and information on supportive treatment (e.g. by administration of supplemental oxygen) are provided in SmPC sections 4.4 and 4.8. <p>Other routine risk minimisation measures beyond the Product Information:</p> <ul style="list-style-type: none"> • Testosterone 1000 mg/4ml solution for injection is a medicinal product subject to medical prescription, for use as directed by medical practitioner. <p>Additional risk minimisation measures: Educational Brochure (Administration Guide)</p>
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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 1000 mg/4ml solution for injection.

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

There are no studies required for Testosterone 1000 mg/4ml solution for injection.