

Summary of the Risk Management Plan

for Tostrex 20 mg/g transdermal gel, Tostran 20 mg/g transdermal gel, Fortigel 20 mg/g transdermal gel and Itnogen 20 mg/g transdermal gel (herein referred as testosterone gel)

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

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

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

I. The medicine and what it is used for

Testosterone gel is authorised as a testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.

It contains testosterone as the active substance, and it is for transdermal use.

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

Currently there are no important risks or missing information proposed for testosterone gel.

II.A. List of important risks and missing information

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

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 gel. 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(s)	None
Important potential risk(s)	None
Missing information	None

II.B. Summary of important risk

Not Applicable as no safety concerns are proposed.

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 gel.

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

There are no studies required for testosterone gel.