Summary of risk management plan for Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel testosterone)

This is a summary of risk management plan for Testosterone 16.2 mg/g gel. The RMP details important risks of Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g geland how more information will be obtained about Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel's risks and uncertainties (missing information).

Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel´s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel should be used.

Important new concerns or changes to the current ones will be included in updates of Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel's RMP.

I. The medicine and what it is used for

Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel is authorised for 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 is given by topical administration.

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

Important risks of Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel, 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 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 Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g 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. 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 Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g 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	• None
Important Potential Risk	• None
Missing information	• None

II.B Summary of important risks

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

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 Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel.

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

There are no studies required for Irisel 16,2 mg/g gel, Testosterona Medical Valley 16,2 mg/g gel.