Part VI: Summary of the risk management plan for Delmes (tadalafil)

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

I. The medicine and what it is used for

Delmes 5 mg is indicated in the treatment of erectile dysfunction in adult males.

In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.

Treatment of the signs and symptoms ofbenign prostatic hyperplasia in adult males.

Delmes 10 mg and Delmes 20 mg is indicated in the treatment of erectile dysfunction in adult males. In order for tadalafil to be effective, sexual stimulation is required.

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

Important risks of Delmes together with measures to minimise such risks and the proposed studies for learning more about Delmes'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.

If important information that may affect the safe use of Delmes is not yet available, it is listed under 'missing information' below.

II.AList of important risks and missing information

Important risks of Delmes are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important riskscan be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of. 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);

Summary of safety concerns	
Important identified risks	– None
Important potential risks	– 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 forDelmes .

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

There are no studies required for Delmes .