



Part VI: Summary of the risk management plan

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

Tadalafil Jubilant summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tadalafil Jubilant 2.5 mg – 5 mg – 10 mg and 20 mg film-coated tablets should be used.

I. The medicine and what it is used for

Tadalafil Jubilant film-coated tablets is used for the treatment of erectile dysfunction in adult males (see SmPC for full indication). It contains tadalafil as the active substance and it is given by oral route.

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

Important risks of tadalafil, together with measures to minimise such risks for learning more about tadalafil risks, is 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.

II.A List of important risks and missing information

Important risks of tadalafil 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 tadalafil. 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	<ul style="list-style-type: none">• Priapism• Hypotension/ increased hypotensive effect
Important potential risks	<ul style="list-style-type: none">• Non-arteritic anterior ischemic optic neuropathy (NAION)• Sudden hearing loss
Missing information	<ul style="list-style-type: none">• Characterisation of adverse events in elderly patients (≥ 65 years of age) (ED/BPH indications only)

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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of tadalafil.

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

There are no studies required for tadalafil.