13 Part VI: Summary of the risk management plan (RMP) – Terbinafine hydrochloride, 78.22 mg/ml, Medicated nail lacquer

This is a summary of the RMP for terbinafine hydrochloride, medicated nail lacquer. The RMP details that there are no important risks which have been identified for terbinafine nail lacquer, and there are no uncertainties (missing information) regarding risks.

Terbinafine hydrochloride, medicated nail lacquer's summary of product characteristics (SmPC) gives essential information to healthcare professionals and patients on how terbinafine hydrochloride, medicated nail lacquer should be used.

Important new concerns or changes to the current ones will be included in updates of the terbinafine hydrochloride, medicated nail lacquer's RMP.

13.1 Part VI: I. The medicine and what it is used for

Terbinafine hydrochloride is indicated for mild to moderate fungal infections of the nails caused by dermatophytes and/or other terbinafine-sensitive fungi. Terbinafine hydrochloride is indicated in adults.

It contains terbinafine hydrochloride as active substance and is intended for use on fingernails, toenails, and immediately adjacent skin (lateral and proximal nailfolds, hyponychium) as 78.22 mg/ml, medicated nail lacquer.

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

There were no important identified/potential risks or missing information identified for terbinafine hydrochloride, medicated nail lacquer, however if any new concerns are identified measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Reports (PSURs) assessment (if applicable) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of Terbinafine hydrochloride, medicated nail lacquer are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely applied. 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 Terbinafine hydrochloride, medicated nail lacquer. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risk	None
Important potential risk	None
Missing information	None

13.2.2. Part VI – II.B: Summary of important risks

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

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of terbinafine hydrochloride, medicated nail lacquer.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for terbinafine hydrochloride, medicated nail lacquer.