PART VI- Summary of the risk management plan

Summary of risk management plan for Ivermectin G.L. 3 mg Tabletten

This is a summary of the risk management plan (RMP) for Ivermectin G.L. 3 mg-Tabletten**.**

The RMP details important risks of Ivermectin G.L. 3 mg-Tabletten how these risks can be minimised, and how more information will be obtained about Ivermectin G.L. 3 mg-Tabletten risks and uncertainties (missing information).

Ivermectin G.L. 3 mg-Tabletten summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ivermectin G.L. 3 mg-Tabletten should be used.

I. The medicine and what it is used for

Ivermectin G.L. 3 mg-Tabletten is authorised for the treatment of gastrointestinal strongyloidiasis, suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti, human sarcoptic scabies (see SmPC for the full indication). It contains Ivermectin 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 Ivermectin G.L. 3 mg-Tabletten 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.

If important information that may affect the safe use of Ivermectin G.L. 3 mg-Tabletten is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ivermectin G.L. 3 mg-Tabletten 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 Ivermectin G.L. 3 mg-Tabletten. 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 3. Summary of Safety Concerns

Important Identified Risks	• Hypersensitivity reactions • Encephalopathy following treatment in patients with heavy Loa loa co-infection
Important Potential Risks	• Lack of efficacy in immunocompromised patients
Missing Information	• Use in lactation • Drug interaction

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 Ivermectin G.L. 3 mg-Tabletten.

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

There are no studies required for Ivermectin G.L. 3 mg-Tabletten.