Part VI: Summary of the risk management plan

Summary of risk management plan for Scabix 3mg tablets (ivermectin)

This is a summary of the risk management plan (RMP) for Scabix, 3 mg tablets. The RMP details important risks of Scabix, 3 mg tablets, how these risks can be minimised, and how more information will be obtained about Scabix 3 mg tablets' risks and uncertainties (missing information).

Scabix 3 mg tablets' summary of produet characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patientson how Scabix, 3mg tablets should be used.

I. The medicine and what it is used for

Scabix, 3 mg tablets is authorised for treatment of gastrointestinal strongyloidiasis (anguillulosis); treatment of diagnosed or suspected microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti and treatment of human sarcoptic scabies (see SmPC for the full indicat ion). 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 Scabix, 3 mg, tablets, together with measures to minimise such risks and the proposed studies for learning more about Scabix, 3 mg tablets' 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 p,ack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status- the way a medicineis 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, including PSUR assessment, sothat immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

If important information that may affect the safe use of Scabix, 3 mg tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Scabix, 3 mg tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal produet can be safely taken. 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 Scabix, 3 mg tablets. 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 longterm use of the medicine);

List of important risks and missing information	
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 interactions

II.B Summary of important risks

The safety information in the proposed Produet nformation 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 Scabix, 3 mg tablets.

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

There are no studies required for Scabix, 3 mg tablets.