Part VI: Summary of the risk management plan

Summary of risk management plan for INTERPRIL

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

INTERPRIL's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how INTERPRIL should be used.

Important new concerns or changes to the current ones will be included in updates of INTERPRIL's RMP.

I. The medicine and what it is used for

INTERPRIL is authorised for treatment of hypertension: mild to moderate high blood pressure in those patients whose blood pressure is not adequately controlled with the sole active ingredient zofenopril (see SmPC for the full indication). It contains zofenopril calcium + hydrochlorothiazide as the active substances and it is given by oral use.

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

Important risks of INTERPRIL, together with measures to minimise such risks and the proposed studies for learning more about INTERPRIL'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 INTERPRIL is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of INTERPRIL 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 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 INTERPRIL. 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	- Hypotension - Hypersensitivity - Second and third trimester of pregnancy - Renal impairment - Angioedema - Neutropenia / agranulocytosis - Dual blockade of the Renin-Angiotensin-System on concomitant use with other RAS-acting agents - Hepatic failure - Electrolyte abnormalities - Foetoxicity - Exacerbation/activation of systemic lupus erythematosus - Myopia and angle-closure glaucoma - Non-melanoma skin cancer (basal cell carcinoma, squamous cell carcinoma)
Important potential risks	- Drug interaction (potassium-sparing diuretics or potassium supplements; diuretics; lithium; antidiabetics) - First trimester of pregnancy - Hyperkalaemia
Missing information	- Use in myocardial infarction patients undergoing haemodialysis or those with hepatic or renal impairment - Use in kidney transplant patients - Drug exposure during lactation - Paediatric population

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 INTERPRIL.

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

There are no studies required for INTERPRIL.