Part VI: Summary of the risk management plan

Summary of risk management plan for Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets

This is a summary of the risk management plan (RMP) for Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets. The RMP details important risks of Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets, how these risks can be minimised and how more information will be obtained about Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets risks and uncertainties (missing information).

Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets RMP.

I. The medicine and what it is used for

Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets is authorised for:

- Symptomatic treatment of anxiety in adults.
- Symptomatic treatment of pruritus associated with urticaria in adults, adolescents and children (≥5-11 years).

It contains Hydroxyzine as the active substance and it is given by oral route of administration.

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

Important risks of Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets, 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

II.A List of important risks and missing information

Important risks of Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets 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 Hydroxyzine Medical Valley 10mg and 25mg Film-coated 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 long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• Hypersensitivity reactions • Cardiac dysrhythmias/QT prolongation • Convulsions • Anticholinergic effect • Interaction with alcohol • Use in patients with moderate or severe renal impairment • Use in patients with hepatic impairment • Use in elderly patients • Use in patients with electrolyte imbalances
Important potential risks	• Cerebrovascular events in patients with risk of stroke
Missing information	• None

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 authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets.

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

There are no studies required for Hydroxyzine Medical Valley 10mg and 25mg Film-coated Tablets.