Part VI: Summary of the risk management plan

Summary of risk management plan for Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablets. The RMP details important risks of Valsartan/Hydrochlorothiazide Jubilant film-coated tablets, how these risks can be minimised, and how more information will be obtained about Valsartan/Hydrochlorothiazide Jubilant film-coated tablets risks and uncertainties (missing information).

Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablet summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablet should be used.

Important new concerns or changes to the current ones will be included in updates of Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablet RMP.

I. The medicine and what it is used for

Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablets is used for the treatment of essential hypertension in adults.

Valsartan/Hydrochlorothiazide Jubilant fixed-dose combination is indicated in patients whose blood pressure is not adequately controlled on valsartan or hydrochlorothiazide monotherapy.

It contains Valsartan &Hydrochlorothiazide 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 Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablets, together with measures to minimise such risks, is 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 Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg 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 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 Valsartan/Hydrochlorothiazide. 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 • Serum electrolyte changes • Renal impairment (especially in patients with renal artery stenosis, pre-existing renal impairment, heart failure, post-myocardial infarction, dual blockade of RAAS) • Teratogenicity
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the 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 Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablets.

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

There are no on-going or closed studies for Valsartan/Hydrochlorothiazide Jubilant 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg & 320 mg/25 mg film-coated tablets.