Summary of Risk Management Plan for Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets

This is a summary of the risk management plan (RMP) for Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets. The RMP details important risks of Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets, how these risks can be minimised, and how more information will be obtained about Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets risks and uncertainties (missing information).

Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets should be used.

Important new safety concerns or changes to the current ones will be included in updates of Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets RMP.

I. The medicine and what it is used for

Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets is indicated for the treatment of:

- Hypertension

  Treatment of essential hypertension in adults.

- Cardiovascular prevention

  Reduction of cardiovascular morbidity in adults with:

  i) Manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease)

  or

  ii) Type 2 diabetes mellitus with documented target organ damage.

Telmisartan Jubilant 20 mg, 40 mg and 80 mg tablets contains Telmisartan 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 Telmisartan Jubilant 20 mg, 40 mg and 80 mg 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 minimization 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 Telmisartan Jubilant 20 mg, 40 mg and 80 mg 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 Telmisartan Jubilant 20 mg, 40 mg and 80 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 long-term use of the medicine).

Summary of safety concerns	
Important identified risks	• None
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 (Micardis tablets of Boehringer Ingelheim International GmbH).

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 Telmisartan Jubilant 20 mg, 40 mg, and 80 mg tablets.

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

There are no studies required for Telmisartan Jubilant 20 mg, 40 mg, and 80 mg tablets.