

Part VI: Summary of the risk management plan

Summary of risk management plan for Bisoprolol Medical Valley (Bisoprolol fumarate)

This is a summary of the risk management plan (RMP) for Bisoprolol Medical Valley. The RMP details important risks of Bisoprolol Medical Valley and how more information will be obtained about Bisoprolol Medical Valley's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Bisoprolol Medical Valley is authorised for hypertension; angina pectoris as well as for treatment of stable chronic heart failure with impaired systolic left ventricular function (see SmPC for the full indication). It contains Bisoprolol fumarate as the active substance and it is given by film-coated tablet.

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

Important risks of Bisoprolol Medical Valley, together with measures to minimise such risks and the proposed studies for learning more about Bisoprolol Medical Valley'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.

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*.

If important information that may affect the safe use of Bisoprolol Medical Valley is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Bisoprolol Medical Valley 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 Bisoprolol Medical Valley. 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	<ul style="list-style-type: none"> • Bradycardia • Aggravation (/worsening) of chronic heart failure • Bronchospasm (patients with bronchial asthma or chronic obstructive pulmonary disease) • Hypotension • Decreased diabetic control and masking of hypoglycemic effects • Syncope
Important potential risks	<ul style="list-style-type: none"> • Renal failure • Toxic skin reactions • Fibrosis conditions (Peyronie's disease, retroperitoneal fibrosis, pulmonary fibrosis) • Interstitial lung disease/Interstitial pneumonitis <p>Fatal hepatotoxicity</p>
Missing information	<ul style="list-style-type: none"> • Children and adolescents under 18 years of age

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

Not applicable.

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 Bisoprolol Medical Valley.

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

There are no studies required for Bisoprolol Medical Valley.