

Part VI: Summary of the risk management plan**Summary of risk management plan for Dalbavancin Bioglan**

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

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

I. The medicine and what it is used for

Dalbavancin Bioglan is authorised for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients aged 3 months and older (see SmPC for the full indication). It contains dalbavancin hydrochloride as the active substance and it is given by intravenous use considering that each vial contains 500 mg of dalbavancin hydrochloride with a final concentration of 20 mg/ml after reconstitution.

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

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

II.A List of important risks and missing information

Important risks of Dalbavancin Bioglan 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 Dalbavancin Bioglan. 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	Emergence of resistance
	Pseudomembranous colitis
	Hypersensitivity
Important potential risks	Hepatic disorder
	Ototoxicity
	Nephrotoxicity
	Haematologic effects
Missing information	Use in immunocompromised patients
	Use in patients with moderate and severe hepatic impairment
	Use in patients with a CrCl<30 ml/min receiving haemodialysis
	Paediatric use
	Use in pregnant and lactating women

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 Dalbavancin Bioglan.

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

There are no studies required for Dalbavancin Bioglan.