GlaxoSmithKline AG

Swiss Summary of the Risk Management Plan (RMP) for

BEXSERO (Meningococcal group B Vaccine (rDNA, component, adsorbed))

RMP Summary: Version 2, March 2021
EU RMP: Version 9.0, 13 November 2020

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Bexsero is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Bexsero in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

GlaxoSmithKline AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Bexsero.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for *Bexsero* (Meningococcal group B vaccine, (rDNA, component, adsorbed)

This is a summary of the risk management plan (RMP) for *Bexsero*. The RMP details important risks of *Bexsero*, how these risks can be minimised, and how more information will be obtained about *Bexsero* 's risks and uncertainties (missing information).

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

This summary of the RMP for *Bexsero* should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of *Bexsero*'s RMP.

I. The medicine and what it is used for

Bexsero is authorised for invasive disease caused by *N. meningitidis* group B (see SmPC for the full indication). It contains three *N. meningitidis* recombinant proteins: NHBA (rp287-953), NadA (rp961c) and fHbp (rp936-741), formulated with OMV from *N. meningitidis* serogroup B strain NZ98/254, containing PorA P1.4 as the active substances and it is given by deep intramuscular injection.
Further information about the evaluation of *Bexsero*'s benefits can be found in *Bexsero*'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: 'Internet site'ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&mid=WC0b01ac058001d124'.

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

Important risks of *Bexsero*, together with measures to minimise such risks and the proposed studies for learning more about *Bexsero*'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, including PSUR assessment - 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 *Bexsero* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Bexsero* 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 *Bexsero*. 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	None
Important potential risks	Arthritis
Missing information	Elderly subjects Immuno-compromised subjects

II.B Summary of important risks

Important Potential Risk: Arthritis	
Evidence for linking the risk to the medicine	Patients vaccinated with *Bexsero* are not known to be at increased risk of this event as a result of vaccination. Rather, this event is considered a potential risk with *Bexsero* because it has been observed after *Bexsero* but it is unknown if *Bexsero* is the cause.
Risk factors and risk groups	Advancing age; gender (more common in women); genetic (specific genes are associated with a higher risk of certain types of arthritis, such as rheumatoid arthritis, systemic lupus erythematous, and ankylosing spondylitis); family history or past history of arthritis; overweight and obesity; joint injuries and joint prosthesis; infections; smoking, intravenous drug abuse, alcoholism, diabetes; exposure to silica dust; dietary intake of vitamin D, antioxidants, fish, protein, and iron.
Risk minimisation measures	No risk minimisation measures

Additional pharmacovigilance activities	None

Missing information: Elderly subjects	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 (PL section 2) with the warning that there are no data on the use of *Bexsero* in adults above 50 years of age Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

Missing information: Immuno-compromised subjects	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 (PL section 2) warning that it is possible that the effectiveness of *Bexsero* is reduced in subjects with weakened immunity Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

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 *Bexsero*.

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

There are no studies required for *Bexsero*