Summary of the Risk Management Plan (RMP) for VeraSeal® (Human fibrinogen/Human thrombin)

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Disclaimer:

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 minimise them.

The RMP summary of VeraSeal® 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 VeraSeal® in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Janssen-Cilag AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of VeraSeal®.

Summary of risk management plan for VeraSeal®

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

VeraSeal® Package Information and its patient information give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for VeraSeal should be read in 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 VeraSeal's RMP.

I. The medicine and what it is used for

VeraSeal® is indicated as a supportive treatment in adults and children where standard surgical techniques are insufficient: for improvement of haemostasis, and as a suture support in vascular surgery. It contains Fibrinogen (Human) and Thrombin (Human) as the active substances and it is given as a solution for sealant.

Further information about the evaluation of VeraSeal's benefits can be found in VeraSeal's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of VeraSeal®, together with measures to minimise such risks and the proposed studies for learning more about VeraSeal® 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 Insert and Patient Information 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 VeraSeal® is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of VeraSeal® 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 VeraSeal®. 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.

List of important risks and missing information	
Important identified risks	• None identified
Important potential risks	• None identified
Missing information	• None identified

II.B Summary of important risks

There are no important identified, potential risks or missing information for VeraSeal®. No safety concerns identified.

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 VeraSeal®.

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

There are no studies required for VeraSeal®.