RISK MANAGEMENT PLAN - PART VI

SUMMARY OF THE RISK MANAGEMENT PLAN

Active substance(s) (INN or common name)	**Purified rabies vaccine for human use prepared on vero cell culture (Rabies (VERO) vaccine)**
Product's concerned (Brand name(s))	**VERORAB®/VACCIN RABIQUE PASTEUR®**
Name of Marketing Authorization Holder or Applicant	**Sanofi Pasteur** **14 Espace Henry Vallee** **69007 Lyon - France** **Phone: +33 4 3737 0100** **Fax: +33 4 3737 7737**
Data Lock Point (DLP for this module)	**01-JAN-2020**
Version number of RMP when this module was last updated	**Version 2.1**

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ABBREVIATIONS

DLP:	Data Lock Point
INN:	International Nonproprietary Name
RMP:	Risk Management Plan
SmPC:	Summary of Product Characteristics

Summary of risk management plan for Rabies (VERO) vaccine:

(Rabies Vaccine for Human Use Prepared from Cell Culture [Vero Cells])

This is a summary of the RMP for Rabies (VERO) vaccine. The RMP details important risks of Rabies (VERO) vaccine how these risks can be minimized, and how more information will be obtained about Rabies (VERO) vaccine's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Rabies (VERO) vaccine's RMP.

VI.1 THE MEDICINE AND WHAT IT IS USED FOR

Rabies (VERO) vaccine is indicated for pre-exposure and post-exposure prophylaxis against rabies in all age groups.

VI.2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERISE THE RISKS

Important risks of Rabies (VERO) vaccine, together with measures to minimize such risks and the proposed studies for learning more about Rabies (VERO) vaccine's risks, are outlined in the next sections.

Measures to minimize 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 authorized 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

VI.2.1. List of important risks and missing information

Important risks of Rabies (VERO) vaccine are risks that need special risk management activities to further investigate or minimize 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 Rabies (VERO) vaccine. 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 (eg, on the long-term use of the medicine).

Table 1 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

VI.2.2. Summary of important risks

Not applicable

VI.2.3. Post-authorization development plan

VI.2.3.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Rabies (VERO) vaccine.

VI.2.3.2 Other studies in post-authorization development plan

There are no studies required for Rabies (VERO) vaccine.

REFERENCES

None