Summary of the Risk Management Plan (RMP) for ADACEL POLIO®

ADACEL POLIO® (Tetanus, Diphtheria, Pertussis (Acellular Component), Poliomyelitis (Inactivated) Vaccine)
Marketing Autorisation Holder : sanofi-aventis (suisse) sa
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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 minimize them. The RMP summary of ADACEL POLIO® 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 medicament" 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 ADACEL POLIO® in Switzerland is the "Arzneimittelinformation/ Information sur le medicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Sanofi-aventis (suisse) sa is fully responsible for the accuracy and correctness of the content of this published summary RMP of ADACEL POLIO®.

1. THE MEDICINE AND WHAT IT IS USED FOR

ADACEL POLIO is indicated for booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis in persons from the 4th birthday.

ADACEL POLIO should be used in accordance with official national recommendations.

ADACEL POLIO should not be used for basic immunization in children up to 4 years of age.

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

Information about adverse reactions is collected continuously and regularly analysed, including Periodic Benefit-Risk Evaluation Report (PBRER) assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

The following measures constitute routine risk minimization measures to minimize the risks identified for medicinal products:

- 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.

There are no important risks of ADACEL POLIO that require additional measures to minimize such risks or additional studies for learning more about these risks. Therefore they are not included in the RMP.

If important information that may affect the safe use of ADACEL POLIO is not yet available, it is listed under 'missing information' outlined in the next section.

2.1. List of important risks and missing information

Missing information refers to topics or certain populations for which there is no or limited data regarding potential adverse effect of the product, and there is an expectation that future feasible additional pharmacovigilance activities may better characterize the safety.

Table 1 - List of important risks and missing information

Important identified risks	None
Important potential risk	None
Missing information	None

2.2. Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

There are neither important identified or potential risks, nor missing information for ADACEL POLIO.

2.3. Post-authorisation development plan

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 ADACEL POLIO.

2.3.2 Other studies in post-authorisation development plan

There are no studies required for ADACEL POLIO.

REFERENCES

N/A