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

ADACEL® (DIPHTHERIA-2/TETANUS/5 AC PERTUSSIS VACCINE)

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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® 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® 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®.

1. THE MEDICINE AND WHAT IT IS USED FOR

Adacel is indicated for booster vaccination against diphtheria, tetanus, pertussis, in persons from the 4th birthday.

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

Important risks of ADACEL, together with measures to minimize such risks and the proposed studies for learning more about ADACEL'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 SmPC addressed to patients and HCPs;
- 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.

There are no important risks of Tetanus diphtheria acellular pertussis with 5 acellular pertussis components (Sanofi Pasteur) (ADACEL) 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report 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 ADACEL is not yet available, it is listed under "missing information" outlined in the next section.

2.1. List of important risks and missing information

Important risks of ADACEL 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 Tradename. 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 topics or certain populations for which there is no or limited data available 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

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

2.3. Post-authorisation development plan

2.3.1 Studies which are conditions of the marketing authorization

The following study is conducted as a condition of the marketing authorization:

Table 2 – Studies which are conditions of the marketing authorization

Pregnancy registry
Purpose of the study: Obtain additional safety data in pregnant women and newborns exposed in postmarketing experience.

2.3.2 Other studies in post-authorisation development plan

There are no studies required for ADACEL.

REFERENCES

N/A