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

BEYFORTUS® (Nirsevimab)
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 BEYFORTUS® 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 BEYFORTUS® in Switzerland is the "Arzneimittelinformation/ Information sur le medicament" (see www.swissmedic.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 BEYFORTUS®.

1. THE MEDICINE AND WHAT IT IS USED FOR

According to Swiss label

Beyfortus is used to prevent lower respiratory tract disease caused by respiratory syncytial virus (RSV) in:

i. Newborns and infants before or during their first RSV season.

ii. Infants up to 24 months of age who are still susceptible to severe RSV disease in their second RSV season (see “Warnings and precautions”, “Clinical efficacy” and “Pharmacokinetics”).

Beyfortus should be used according to official recommendations.

According to EU SmPC

Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tractdisease in neonates and infants during their first RSV season.
Beyfortus should be used in accordance with official recommendations.

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu:

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

Important risks of nirsevimab, together with measures to minimise such risks and the proposed studies for learning more about nirsevimab'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 product information addressed to caregiver for infants 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 (eg, 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 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 nirsevimab is not yet available, it is listed under ‘missing information’ below.

2.1. List of important risks and missing information

Important risks of nirsevimab are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered (Table VI-1). 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 nirsevimab. 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 VI-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 no important risks for nirsevimab as per section 2.1.

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 authorisation or specific obligation of nirsevimab.