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Summary of Risk Management Plan (RMP)

Incellipan

(aH5N1c pandemic influenza vaccine, prepared in cell cultures, adjuvanted)

Suspension for injection

Influenza virus surface antigen (haemagglutinin and neuraminidase), inactivated, of the type A/turkey/Turkey/1/2005 NIBRG-23 (H5N1)

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Based on CSL Seqirus EU RMP version 1.0
Vifor (International) Inc., Switzerland

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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 Incellipan (aH5N1c pandemic influenza vaccine) 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 authorisation.

Please note that the reference document which is valid and relevant for the effective and safe use of Incellipan in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorised by Swissmedic. Vifor (International) Inc. is fully responsible for the accuracy and correctness of the content of the published summary RMP of Incellipan.

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Summary of Risk Management Plan for Incellipan (Pandemic influenza vaccine aH5N1c)

This is a summary of the risk management plan (RMP) for Incellipan (Pandemic influenza vaccine aH5N1c). The RMP details important risks of Incellipan, how these risks can be minimised, and how more information will be obtained about Incellipan risks and uncertainties (missing information).

Incellipan summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Incellipan should be used.

This summary of the RMP for Incellipan should be read in the 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 safety concerns or changes to the current ones will be included in updates of Incellipan RMP.

I. The medicine and what it is used for

Incellipan is indicated for active immunisation against influenza in an officially declared pandemic. Incellipan should be used in accordance with official recommendations. It contains an inactivated, surface antigen monovalent, influenza vaccine adjuvanted with MF59, prepared in cell cultures. It is to be administered as two doses of 0.5 ml by intramuscular injection, 21 days apart. For those over 12 months of age, the preferred injection site is the region of the deltoid muscle of the upper arm; for those 6 to less than 12 months of age, the preferred injection site is the anterolateral thigh. Further information about the evaluation of Incellipan benefits can be found in Incellipan 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 Incellipan together with measures to minimise such risks and the proposed studies for learning more Incellipan 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 SmPC 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.

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II.A List of important risks and missing information

Important risks 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 safety concerns for which there is sufficient proof of a link with the use of Incellipan. Potential risks are safety 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 (e.g. on the long-term use of the medicine).

Table Part VI. 1: Summary of Safety Concerns for Incellipan

Important identified risk	None
Important potential risk	Neuritis Convulsions Encephalomyelitis Vasculitis Guillain-Barré Syndrome Demyelination Bell's palsy Immune thrombocytopenia
Missing information	Use in pregnancy

II.B Summary of Safety Concerns

Table Part VI. 2: Summary of Safety Concerns for Incellipan

Neuritis	
Risk minimisation measures	Routine risk minimisation measures: *Incellipan SmPC: Section 4.8* *Incellipan PL: Section 4* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*

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Convulsions	
Risk minimisation measures	Routine risk minimisation measures: *Incellipan SmPC: Sections 4.4 and 4.8* *Incellipan PL: Sections 2 and 4* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*
Encephalomyelitis	
Risk minimisation measures	Routine risk minimisation measures: *Incellipan SmPC: Section 4.8* *Incellipan PL: Section 4* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*
Vasculitis	
Risk minimisation measures	Routine risk minimisation measures: *Incellipan SmPC: Section 4.8* *Incellipan PL: Section 4* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*

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Guillain-Barré Syndrome	
Risk minimisation measures	Routine risk minimisation measures: *Incellipan SmPC: Section 4.8* *Incellipan PL: Section 4* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*
Demyelination	
Risk minimisation measures	Routine risk minimisation measures: *None; included as a potential safety concern based on pharmacological class effects* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*
Bell's palsy	
Risk minimisation measures	Routine risk minimisation measures: *None; included as a potential safety concern based on pharmacological class effects* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*

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Immune thrombocytopenia	
Risk minimisation measures	Routine risk minimisation measures: *None; included as a potential safety concern based on pharmacological class effects* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *EPSS (in situation of pandemic)* Additional pharmacovigilance activities: *None*
Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures: Pregnancy is described in: *Incellipan SmPC: Section 4.6* *Incellipan PL: Section 2* Additional risk minimisation measures: *No additional measures*
Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* Additional pharmacovigilance activities: *V89_20OB (in situation of pandemic)*

S-PSUR: simplified Periodic Safety Update Report, SmPC: Summary of Product Characteristics, PL: Package Leaflet

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no safety studies imposed as condition of the marketing authorisation (category 1), or as a specific obligation in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances (category 2).

An updated RMP with further details on additional pharmacovigilance activities will be submitted to competent authorities once a pandemic is declared.

A non-interventional (observational) study of vaccine effectiveness in children and adults* against laboratory confirmed influenza will be performed during the next declared pandemic as a specific obligation in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances, in accordance with the Guideline on Influenza vaccine (EMA/CHMP/VWP/457259/2014).

**The age population may be subject to change based on Health Authority recommendations once pandemic is declared*

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

It is considered that for the majority of the safety concerns, routine pharmacovigilance activities alone will be sufficient. However, in the situation of a pandemic, required Category 3 study V89_20B, for the missing information Use in pregnancy, is planned:

V89_20OB is a postmarketing, observational cohort study to evaluate the safety of adjuvanted pandemic influenza vaccine A/H5N1c* in pregnant women (pregnancy registry). This study is planned in case of pandemic and will follow from enrolment to pregnancy outcome and in live-born infants until 3 months of age.

*The strain is subject to change to be matched with the next pandemic strain

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