Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Incellipan suspension for injection in pre-filled syringe

A/TURKEY/TURKEY/1/2005 (H5N1)-LIKE STRAIN (NIBRG-23), INFLUENZA VIRUS STRAINS INACTIVATED

PLGB 47991/0016

SEQIRUS UK LIMITED

LAY SUMMARY

Incellipan suspension for injection in pre-filled syringe A/TURKEY/TURKEY/1/2005 (H5N1)-LIKE STRAIN (NIBRG-23), INFLUENZA VIRUS STRAINS INACTIVATED

This is a summary of the Public Assessment Report (PAR) for Incellipan suspension for injection in pre-filled syringe. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Incellipan in this lay summary for ease of reading.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the European Medicines Agency (EMA), with the procedure number EMEA/H/C/006051/0000. The procedure followed route B.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended).

For practical information about using Incellipan, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Incellipan and what is it used for?

This application was a full-dossier application. This means that the results of pharmaceutical, non-clinical and clinical tests have been submitted to show that this vaccine is suitable for treating the specified indication.

Incellipan is a vaccine intended to be given to prevent influenza (flu) in an officially declared pandemic.

Pandemic flu is a type of influenza that happens at intervals that vary from less than 10 years to many decades. It spreads rapidly around the world. The signs of pandemic flu are similar to those of ordinary flu but may be more serious.

Incellipan is used to prevent flu caused by the H5N1 type of the virus.

How does Incellipan work?

When a person is given the vaccine, the body’s natural defence system (immune system) produces its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

How is Incellipan used?

The pharmaceutical form of this vaccine is a suspension for injection and the route of administration is intramuscular (into a muscle).

This vaccine will be administered by a doctor or nurse in accordance with official recommendations.

For adults and children 6 months of age and older, one dose (0.5 ml) of the vaccine will be injected into the upper arm (deltoid muscle) or upper thigh, depending on the age and muscle

mass of the person receiving the vaccine. A second dose of vaccine should be given after an interval of at least 3 weeks.

For further information on how Incellipan is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This vaccine can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning their vaccine.

What benefits of Incellipan have been shown in studies?
Incellipan is effective at triggering the production of antibodies against the H5N1 subtype of the influenza A virus.

A main study involved around 3,200 adults who received 2 doses of Incellipan or placebo (a dummy vaccine) 3 weeks apart. Three weeks after the second dose, 67% of people who received Incellipan achieved seroconversion against the H5N1 strain in the vaccine, compared with 1% of those who received placebo. Six months after second dose, about 12% of people given Incellipan still showed seroconversion compared with about 1% of people given placebo.

Another study involved about 330 children aged 6 months to 17 years who were given 2 doses of Incellipan 3 weeks apart. Three weeks after the second dose, about 96% of children given Incellipan had adequate levels of antibodies against the H5N1 strain in the vaccine.

Based on these results the vaccine is expected to offer protection against influenza disease caused by a pandemic influenza strain.

What are the possible side effects of Incellipan?
For the full list of all side effects reported with this vaccine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the vaccine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Why was Incellipan approved?
MHRA decided that the benefits are greater than the risks and recommended that this medicinal product can be approved for use.

Incellipan has been authorised with a conditional marketing authorisation (CMA). CMAs are intended for medicinal products that address an unmet medical need, such as a lack of alternative therapy for a serious and life-threatening disease. CMAs may be granted where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon.

Incellipan has been authorised with the condition to perform further studies. See section below "What measures are being taken to ensure the safe and effective use of Incellipan?"

What measures are being taken to ensure the safe and effective use of Incellipan?
As for all newly-authorised medicines and medicinal products, a Risk Management Plan (RMP) has been developed for Incellipan. The RMP details the important risks of Incellipan, how these risks can be minimised, any uncertainties about Incellipan (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Incellipan:

Summary of safety concerns	
Important identified risks	None
Important potential risks	Neuritis Convulsions Encephalomyelitis Vasculitis Guillain-Barré Syndrome Demyelination Bell's palsy Immune thrombocytopenia
Missing information	Use in pregnancy and lactation

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, study V89_20B is planned to address the missing information 'use in pregnancy and lactation'.

V89_20OB is a post-marketing, observational cohort study to evaluate the safety of Incellipan 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.

Incellipan was granted a conditional marketing authorisation. The conditions of the marketing authorisation are that in the case of a pandemic, a vaccine effectiveness study will be conducted by the company responsible for this vaccine. The study would be a non-interventional observational effectiveness study in children and adults against laboratory confirmed influenza, with the objective to perform an analysis of pandemic vaccine effectiveness against laboratory confirmed influenza for Incellipan versus no vaccination.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Incellipan are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Incellipan
A marketing authorisation was granted in Great Britain on 13 November 2024. The full PAR for Incellipan follows this summary. This summary was last updated in January 2025.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Incellipan suspension for injection in pre-filled syringe (PLGB 47991/0016) could be approved.

The product was approved for active immunisation against influenza in an officially declared pandemic. Incellipan should be used in accordance with official recommendations.

The active components of the vaccine are influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of strain A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23).

Pandemic preparedness vaccines contain influenza antigens that are different from those in the currently circulating influenza viruses. These antigens can be considered as “novel” antigens and simulate a situation where the target population for vaccination is immunologically naïve. Data obtained with the pandemic preparedness vaccine will support a vaccination strategy that is likely to be used for the pandemic vaccine: clinical immunogenicity, safety and reactogenicity data obtained with pandemic preparedness vaccines are relevant for the pandemic vaccines.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the European Medicines Agency (EMA), with the procedure number EMEA/H/C/006051/0000. The procedure followed route B.

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority’s website.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended).

Incellipan suspension for injection in pre-filled syringe has been authorised as a conditional marketing authorisation (CMA). CMAs are granted in the interest of public health and are intended for medicinal products that fulfil an unmet medical need and the benefit of immediate availability outweighs the risk posed from less comprehensive data than normally required. Unmet medical needs include, for example, treatment or diagnosis of serious and life-threatening diseases where no satisfactory treatment methods are available.

CMAs may be granted where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon. Adequate evidence of safety and efficacy to enable the MHRA to conclude that the benefits are greater than the risks is required and has been provided for Incellipan suspension for injection in pre-filled syringe. The CMA for Incellipan suspension for injection in pre-filled syringe, including the provision of any new information, will be reviewed every year and this report will be updated as necessary.

In line with the legal requirements for children's medicinal products, the application included a licensing authority decision on the agreement of a paediatric investigation plan (PIP) MHRA-101268-PIP01-23. At the time of the submission of the application the PIP was not yet completed as some measures were deferred.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 13 November 2024.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory. The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory. The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory. The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. In addition to routine pharmacovigilance and risk minimisation measures, additional pharmacovigilance activities have been proposed (see following table for the risk minimisation measures and pharmacovigilance activities for all safety concerns).

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*
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*

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
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 and lactation	
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

This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable. The non-clinical and clinical data submitted have shown the positive benefit/risk of this product in the treatment of active immunisation against influenza in an officially declared pandemic.

Incellipan suspension for injection in pre-filled syringe has been authorised with a conditional marketing authorisation (CMA). The Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to confirm the efficacy of Incellipan, the MAH should conduct a non-interventional observational effectiveness study in children and adults against laboratory confirmed influenza during the next declared pandemic.	30/09/2025

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved GB versions of the SmPC and PIL for this product are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**