



# **Public Assessment Report**

## **National Procedure**

**Influenza vaccine TIV MYL suspension for  
injection in pre-filled syringe  
(influenza vaccine, surface antigen, inactivated)**

**influenza virus surface antigens (inactivated)  
(haemagglutinin and neuraminidase)  
A/VICTORIA/4897/2022 (H1N1)PDM09-LIKE  
STRAIN**

**(A/VICTORIA/4897/2022 IVR-238)  
A/DARWIN/9/2021 (H3N2)-LIKE STRAIN  
(A/DARWIN/9/2021, SAN-010)**

**B/AUSTRIA/1359417/2021-LIKE STRAIN  
(B/AUSTRIA/1359417/2021 BVR-26)**

**PLGB 46302/0251**

**Mylan Products Limited**

## LAY SUMMARY

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(influenza vaccine, surface antigen, inactivated)  
influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase)  
A/Victoria/4897/2022 (H1N1)pdm09-like strain  
(A/Victoria/4897/2022, IVR-238)  
A/Darwin/9/2021 (H3N2)-like strain (A/Darwin/9/2021, SAN-010)  
B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)**

This is a summary of the Public Assessment Report (PAR) for Influenza vaccine TIV MYL 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 Influenza vaccine TIV MYL in this lay summary for ease of reading.

This product has been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for Great Britain (consisting of England, Scotland and Wales). This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 16 February 1998 (NL/H/0137/001/DC). This is known as the DC Reliance Procedure.

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 Influenza vaccine TIV MYL, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

### **What is Influenza vaccine TIV MYL and what is it used for?**

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

Influenza vaccine TIV MYL helps to protect adults and children from 6 months of age against influenza (flu), particularly in subjects who run a high risk of associated complications.

### **How does Influenza vaccine TIV MYL work?**

Influenza vaccine TIV MYL provides active immunisation against three influenza virus strains by inducing the immune system (the body's natural defence system) to produce its own protection (antibodies) against influenza viruses.

### **How is Influenza vaccine TIV MYL used?**

The pharmaceutical form of this medicine is a suspension for injection and the route of administration is intramuscular (into a muscle) or deep subcutaneous (under the skin) injection.

The main dosing recommendations are as follows:

Adults receive one 0.5 ml dose.

Children from 6 months to 17 years receive one 0.5 ml dose.

Children less than 9 years of age, who have not previously been vaccinated with a seasonal influenza vaccine: a second dose should be given after an interval of at least 4 weeks. For infants less than 6 months of age, the safety and efficacy of Influenza vaccine TIV MYL have not been established.

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

This medicine can only be obtained with a prescription.

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

**What benefits of Influenza vaccine TIV MYL have been shown in studies?**

To date, 86 clinical studies have been performed over a 30-year period, including more than 9,000 subjects, which confirmed the immunogenicity of the Influenza vaccine TIV MYL produced as a subunit vaccine. The efficacy data are described in the approved product information.

**What are the possible side effects of Influenza vaccine TIV MYL?**

For the full list of all side effects reported with this medicine, 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 medicine. 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.

The most common side effects of the Influenza vaccine TIV MYL (which may affect more than 1 in 10 people) are as follows:

***Adults and elderly:***

- headache<sup>a</sup>
- fatigue
- local reaction: vaccination site pain

<sup>a</sup> In elderly adults (≥ 61 years) reported as common

***Children (6 months to 17 years of age):***

**Side effects that occurred in children 6 to 35 months of age:**

- drowsiness
- sweating
- appetite loss
- diarrhoea, vomiting
- irritability/fussiness
- fever
- local reactions: pain, redness

**Side effects that occurred in children 3 - 5 years of age:**

- drowsiness
- appetite loss
- irritability/fussiness
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected
  
- **Side effects that occurred in children 6 - 17 years of age:**
- headache
- nausea, abdominal pain, diarrhoea, vomiting
- muscular pain (myalgia)
- fatigue, generally feeling unwell (malaise)
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected

### **Why was Influenza vaccine TIV MYL approved?**

MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

### **What measures are being taken to ensure the safe and effective use of Influenza vaccine TIV MYL?**

As for all newly-authorised medicines, an Risk Management Plan (RMP) has been developed for Influenza vaccine TIV MYL. The RMP details the important risks of Influenza vaccine TIV MYL, how these risks can be minimised, any uncertainties about Influenza vaccine TIV MYL (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Influenza vaccine TIV MYL.

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 Influenza vaccine TIV MYL 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 Influenza vaccine TIV MYL**

A marketing authorisation was granted in Great Britain on 05 December 2024.

The full PAR for Influenza vaccine TIV MYL 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 Influenza vaccine TIV MYL suspension for injection in pre-filled syringe (PLGB 46302/0251) could be approved.

The product is approved for the following indications:

Prophylaxis of influenza disease in adults and children from 6 months of age.

Influenza vaccine TIV MYL should be used in accordance with official recommendations.

The name of the active substance is influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase), which belongs to the pharmacotherapeutic group of influenza vaccine.

### Mechanism of action

Influenza vaccine TIV MYL provides active immunisation against three influenza virus strains: an A/(H1N1) strain, an A/(H3N2) strain, and a B strain. It induces humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses.

Specific levels of haemagglutination-inhibition (HI) antibody titre post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HI antibody titres have been used as a measure of vaccine activity.

An immune response is generally obtained within 2 to 3 weeks. The duration of post vaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). This procedure takes into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 16 February 1998 (NL/H/0137/001/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedures, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies 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).

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 05 December 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. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. 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.

**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 products in prophylaxis of influenza disease in adults and children from 6 months of age.

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

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products 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.

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