**Product Insert (PI) for Influenza vaccine**

## 1. NAME OF THE MEDICINAL PRODUCT

Serinflu, suspension for injection
(influenza vaccine, surface antigen, inactivated).

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains*:

| | |
|---|---|
| - A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238) | 15 micrograms HA ** |
| - A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A) | 15 micrograms HA ** |
| - B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26) | 15 micrograms HA ** per 0.5 ml dose |

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin.

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2025/2026 season.

For a full list of excipients see section 6.1.

Serinflu may contain traces of eggs (such as ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin, which are used during the manufacturing process (see section 4.3).

## 3. PHARMACEUTICAL FORM

Suspension for injection in vial; a colourless clear liquid, filled in vial (glass, type I) for single-dose use.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.

Serinflu is indicated in adults and children from 6 months of age.
The use of Serinflu should be based on official recommendations.

### 4.2. Posology and method of administration

Posology
Adults: 0.5 ml.

*Paediatric population*
Children from 36 months onwards: 0.5 ml.

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given, for instructions on administering a 0.25 ml or 0.5 ml dose, see section 6.6. The dose given should be in accordance with existing national recommendations.

For children, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Serinflu in children less than 6 months have not been established. No data are available.

Method of Administration
Immunisation should be carried out by intramuscular or deep subcutaneous injection.

Precautions to be taken before handling or administrating the medicinal product:
For instructions for preparation of the medicinal product before administration, see section 6.6.

### 4.3. Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.

Immunisation shall be postponed in patients with febrile illness or acute infection.

### 4.4. Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Serinflu should under no circumstances be administered intravascularly.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing: see section 4.5.

### 4.5. Interaction with other medicinal products and other forms of interaction

There is no information on administration/possible immune reference of Serinflu with (childhood) vaccines. Therefore, Serinflu should not be given at the same time with other (childhood) vaccines.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the IgM response by the vaccine.

### 4.6. Fertility, pregnancy and lactation

Pregnancy
Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of influenza vaccine do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

Breast-feeding
Serinflu may be used during breast-feeding.

Fertility
No fertility data are available

### 4.7. Effects on ability to drive and use machines

Serinflu has no or negligible influence on the ability to drive and use machines.

### 4.8. Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS
The safety of trivalent inactivated influenza vaccines is assessed in open label, uncontrolled clinical trials performed as annual update requirement, including at least 50 adults aged 18 - 60 years of age and at least 50 elderly aged 61 years or older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies:
very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100).

Tabulated list of adverse reactions:

| Organ class | Very common ≥1/10 | Common ≥1/100, <1/10 | Uncommon ≥1/1,000, <1/100 |
|---|---|---|---|
| Nervous system disorders | | Headache* | |
| Skin and subcutaneous tissue disorders | | Sweating* | |
| Musculoskeletal and connective tissue disorders | | Myalgia, arthralgia* | |
| General disorders and administration site conditions | | Fever, malaise, shivering, fatigue<br>Local reactions: redness, swelling, pain, ecchymosis, induration* | |

* These reactions usually disappear within 1-2 days without treatment

ADVERSE REACTIONS REPORTED FROM POST-MARKETING SURVEILLANCE

Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:
Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:
Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome

Vascular disorders:
Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:
Generalised skin reactions including pruritus, urticaria or non-specific rash

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

### 4.9. Overdose

Overdosage is unlikely to have any untoward effect.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.
Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

### 5.2 Pharmacokinetic properties

Not applicable.

### 5.3 Preclinical safety data

Not applicable.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and water for injections.

### 6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### 6.3 Shelf-life

1 year.
Once the single-dose vial has been penetrated, the vaccine should be used promptly.

### 6.4 Special precautions for storage

Store in a refrigerator **(**+2°C to +8°C**)**.
Do not freeze.
Store in the original package in order to protect from light.

### 6.5 Nature and contents of container

0.5 ml suspension for injection in vial (glass, type I), with bromobutyl stopper, sealed with an aluminium cap, in pack of 1 or 10.
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.

For the administration of a 0.25 ml dose (for children from 6 months to 35 months): use a syringe for injection with a 0.25 ml mark. See also section 4.2.
In case of administration to children aged 6 to 35 months by taking 0.25 ml of this vaccine, the vial containing the remainder must be IMMEDIATELY discarded.

Any unused product or waste material should be disposed of in accordance with local requirements.

### MANUFACTURER

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