PATIENT INFORMATION LEAFLET

TorVaxFlu®, 15 micrograms/0.5 mL+15 micrograms/0.5 mL+15 micrograms/0.5 mL, suspension for injection in a pre-filled syringe

influenza vaccine (split virion, inactivated)

▼ This medicine is under additional monitoring. This allows new safety information to be discovered quickly. You can help with this by reporting any side effects that occur to you. For how to report side effects, see the information at the end of section 4.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep the leaflet. You may need to read it again.
- If you have any additional questions, please ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What TorVaxFlu is and what it is used for

TorVaxFlu is an inactivated influenza vaccine (split virion).
The TorVaxFlu vaccine is intended to protect against influenza in adults aged 18 to 65 years.
The use of TorVaxFlu should be based on official recommendations.
After the application of the TorVaxFlu vaccine the immune system (the body's natural defence) creates its own protection (antibodies) against the disease. None of the vaccine substances can cause the flu.
Influenza is one of the main communicable diseases that threaten the human population, both due to the annual flu epidemics that negatively affect health, and due to the harmful global consequences caused by influenza pandemics. Vaccination is currently the most effective means of preventing influenza infection.
Influenza is a disease that is quickly transmitted and is caused by different types of strains that can change every year. That's why you may need to get vaccinated every year. The greatest risk of getting the flu is during the cold months, between October and March. If you have not been vaccinated against the flu in the fall, it is still reasonable to get vaccinated until the spring, given that there is a risk of infection by that time.
Your doctor will recommend the best time to get vaccinated.
The TorVaxFlu vaccine will protect you against the strains of the three types of virus (two subtypes of strain A, one type of strain B) contained in the vaccine, and this is usually achieved within 3 weeks of application.
The incubation period for the flu is a few days, so if you are exposed to the flu immediately before or after vaccination, there is a possibility of illness.
The vaccine will not protect you from the common cold, although some symptoms are similar to the flu.

2. Before you receive TorVaxFlu

To make sure that TorVaxFlu is right for you, it is important that you tell your doctor or pharmacist if any of the conditions listed below apply to you. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use TorVaxFlu:

- if you are allergic (hypersensitive) to active substances or any of the other ingredients of this medicine (listed in section 6), to egg proteins, feathers and chicken meat, to ovalbumin, neomycin, Triton X-100 and betapropiolactone.
- If you have a disease accompanied by fever or an acute infection, vaccination should be postponed until recovery.

Warnings and precautions:

Talk to your doctor or pharmacist or nurse before taking TorVaxFlu vaccine.
After the vaccine, as with other injectable drugs, a serious allergic reaction (anaphylactic reaction) is possible. The health institution where the vaccination is carried out must enable the provision of appropriate medical treatment in the event of anaphylactic shock.
Vaccinated people should be under the supervision of a doctor for at least 30 minutes after receiving the vaccine.
Talk to your doctor before vaccination:

- If you have a weak immune response (immunodeficiency or taking medicines that affect the immune system) because the response to the vaccine may be insufficient.
- If, for any reason, you donate blood for analysis within a few days of receiving the flu vaccine, please tell your doctor that you have received the vaccine. This is because, in several patients who have previously received the flu vaccine, false-positive blood test results have been observed.
- If you have a bleeding problem or are prone to bruising.

Your doctor will decide if you need to be vaccinated.

Loss of consciousness may occur after any injection, or sometimes before the injection. Therefore, tell your doctor or nurse if you lost consciousness during the previous injection.

TorVaxFlu should not be given intravenously.

As with all vaccines, TorVaxFlu may not provide complete protection for all people who have been vaccinated.

Other medicines and TorVaxFlu

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

TorVaxFlu can be used at the same time as other vaccines if they are given at different sites. It is important to know that side effects can be exacerbated.

The immune response may be impaired if the patient is undergoing immunosuppressive therapy, such as corticosteroids, cytotoxic drugs, or radiotherapy.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking TorVaxFlu.

Data on the use of inactivated influenza vaccine in the world indicate that it can be used in all stages of pregnancy. More extensive safety data are available for the second and third trimesters of pregnancy compared to the first trimester. However, data on the use of influenza vaccine worldwide do not indicate that the vaccine has adverse effects on the foetus or mother.

It is not known whether TorVaxFlu is excreted in human milk, so caution should be exercised if this vaccine is administered to a breast-feeding woman.

Your doctor or pharmacist will decide if you need to receive the TorVaxFlu vaccine.

No data are available on the use of TorVaxFlu during pregnancy and lactation.

<u>Fertility:</u>

No data are available on the effect of TorVaxFlu on human fertility.

Driving and using machines

The TorVaxFlu vaccine has no or negligible influence on the ability to drive and use machines.

3. How to use TorVaxFlu

<u>Dosage:</u>

Adults (aged 18 to 65) receive a single dose of 0.5 mL.

Use in children and adolescents
Safety and efficacy in children and adolescents under 18 years of age have not yet been established.

Method of application
Your doctor will give you the recommended dose of the vaccine by giving an injection intramuscularly (injection into a muscle).
If you have any further questions on the use of this vaccine, ask your doctor or pharmacist.
If you have any further questions on the use of this product, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, TorVaxFlu vaccine can cause side effects, although not everybody gets them.
During clinical trials, the following adverse reactions were observed, which were assessed on the basis of their frequency:

- Very common side effects (may affect more than 1 in 10 patients taking the medicine):
  Headache
  Fatigue
  Local reactions at the site of application: pain, tenderness and redness
- Frequent side effects (may affect up to 1 in 10 patients taking the medicine):
  Fever
  Shivering
  Nausea
  Joint pain (arthralgia)
  Muscle pain (myalgia)
  Local reactions at the site of application: hardening (induration) and swelling
- Rare side effects (may affect up to 1 in 1,000 patients taking the medicine):
  Vomiting
  Pharyngitis (inflammation of the throat)
  Muscle spasm

In addition to the previously mentioned side effects identified in clinical trials, the following side effects of unknown frequency (based on available data) may occur based on literature data, including post-marketing surveillance of inactivated influenza vaccine (cannot be estimated from the available data):

- allergic reactions:

- in rare cases require emergency medical care, due to the inability of the circulatory system to maintain sufficient blood flow through various organs (shock)
- swelling that is most noticeable on the head and neck, including the face, lips, tongue, throat or other part of the body (angioedema), in very rare cases

- skin reactions, which can spread throughout the body, such as itching (pruritus, urticaria), rash
- inflammation of the blood vessels (vasculitis), which can result in a skin rash and, in very rare cases, transient kidney problems
- nerve pain (neuralgia), disturbance in the experience of touch, pain, hot or cold (paraesthesia), convulsions, neurological disorders that can lead to neck stiffness, confusion, insensitivity,

pain and weakness of the limbs, loss of balance, loss of reflex, paralysis of one or the whole body (encephalomyelitis, neuritis, Guillain-Barre syndrome)
- a transient decrease in the number of certain types of cells in the blood, called platelets; and their small number can lead to increased bruising and bleeding (transient thrombocytopenia), transiently swollen lymph nodes in the neck, armpits or groin (transient lymphadenopathy).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting side effects

If you experience any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine. You can report suspicion on side effects to the Medicines and Medical Devices Agency of Serbia (ALIMS):

Medicines and Medical Devices Agency of
Serbia
National Pharmacovigilance Centre
458 Vojvode Stepe St, 11221 Belgrade
Republic of Serbia
website: www.alims.gov.rs
e-mail: nezeljene.reakcije@alims.gov.rs

5. How to store TorVaxFlu

Keep this medicine out of sight and reach of children.

Do not use TorVaxFlu vaccine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store in refrigerator (on 2°C to 8°C), in the original package. Do not freeze.

Unusable medicines are handed over to a pharmacy in which a notice is displayed stating that unusable medicines are collected from citizens in that pharmacy. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What TorVaxFlu contains

The active substance is:

Surface antigens (haemagglutinin and neuraminidase) of influenza virus (split virion, inactivated) of the following strains *:

- A/Victoria/2570/2019 (H1N1)pdm09-like strain (A/Victoria/2570/2019, IVR-215)..... at least 15 micrograms HA **
- A/Cambodia/e0826360/2020 (H3N2) -like strain (A/Cambodia/e0826360/2020, IVR-224)..... at least 15 micrograms HA **
- B/Washington/02/2019-like strain (B/Washington/02/2019, wild type)..... at least 15 micrograms HA **

at a dose of 0.5 mL

* propagated on embryonic chicken eggs from healthy flocks

** hemagglutinin

The vaccine corresponds to the recommendation of the World Health Organization for the Northern Hemisphere and the decision of the European Union for the 2021/2022 season.

The TorVaxFlu vaccine may contain traces of eggs (such as ovalbumin), neomycin, Triton X-100 and betapropiolactone used during the manufacturing process (see *TorVaxFlu vaccine must not be used*).

The TorVaxFlu vaccine does not contain a preservative.

The other ingredients are:
Buffered saline containing: sodium chloride, potassium chloride, disodium phosphate, dihydrate, potassium dihydrogen phosphate and water for injections.

What TorVaxFlu looks like and content of the pack
Suspension for injection in a pre-filled syringe.
After mild swirling, the vaccine is a slightly opalescent whitish liquid.
The inner packaging is a 1 mL clear glass syringe (type I glass) with an integrated needle. A dark grey rubber stopper (bromobutyl) with a plunger nut is used to close the syringe.
The outer package is a collapsible cardboard box containing one pre-filled syringe in a PVC blister and instructions for use.

Authorisation Holder and Manufacturer
Institute of Virology, Vaccines and Sera Torlak
458 Vojvode Stepe St; Belgrade

This leaflet was last revised in
August, 2021.

Medicine dispensing regime:
The medicine can be used in a health institution.

Marketing authorization number and date:
515-01-04295-19-001 dated August 14, 2020

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

Therapeutic indications
Influenza prevention.
The TorVaxFlu vaccine is indicated for the prevention of influenza in adults aged 18 to 65 years.
The use of TorVaxFlu should be based on official recommendations.

Dosage and method of administration
Dosage:
Adults: 0,5 mL.

Paediatric population:
Safety and efficacy in children and adolescents under 18 years of age have not yet been established.

Method of application:
The TorVaxFlu vaccine is given intramuscularly.
Shake before use.
For additional instructions for use of the vaccine, see section *Special precautions for disposal after use (and other instructions for handling).*

List of excipients
Buffered saline containing:
Sodium-chloride,
Potassium-chloride,
Disodium phosphate, dihydrate,
Potassium dihydrogen phosphate,
Water for injections.

Incompatibility
In the absence of compatibility testing, TorVaxFlu should not be mixed with other drugs, serums and vaccines in the same syringe.

Expiration date
9 months.

Special precautions for storage
Store in refrigerator (on 2°C to 8°C), in the original package. Do not freeze.

Nature and content of the package
The inner packaging is a 1 mL clear glass syringe (type I glass) with an integrated needle. A dark grey rubber stopper (bromobutyl) with a plunger nut is used to close the syringe.
The outer package is a collapsible cardboard box containing one pre-filled syringe in a PVC blister and instructions for use.

Special precautions for disposal of a used medicinal product (and other instructions for handling the drug)
It is required that the vaccine reach room temperature before use.
The vaccine should be visually inspected for administration.
Do not use the vaccine if foreign particles are present in the suspension.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.