Package Leaflet – Information for the User

Supemtek® TIVr Solution for injection in pre-filled syringe

Trivalent Influenza Vaccine (recombinant, prepared in cell culture)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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What is in this leaflet:

1. What Supemtek TIVr is and what it is used for
2. What you need to know before you receive Supemtek TIVr
3. How Supemtek TIVr is given
4. Possible side effects
5. How to store Supemtek TIVr
6. Contents of the pack and other information

1. What Supemtek TIVr is and what it is used for

Supemtek TIVr is a vaccine for adults and children who are 9 years of age and older. This vaccine helps to protect you against flu (influenza). Supemtek TIVr is egg-free because of the technology used to produce it.

When a person is given Supemtek TIVr, the body's natural defence (the immune system) produces protection against the influenza virus. None of the ingredients in the vaccine can cause flu.

As with all vaccines, Supemtek TIVr may not fully protect all persons who are vaccinated.

When to have a flu vaccine

Flu can spread very fast.

- It is caused by different types of flu virus that can change every year. This is why you might need to be vaccinated every year.
- The greatest risk of catching flu is during the cold months between October and March.
- If you were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you run the risk of catching flu until then.

Your doctor will be able to recommend the best time to be vaccinated.

2. What you need to know before you receive Supemtek TIVr

Do not use Supemtek TIVr if you are allergic to:

- the active ingredients or any of the other ingredients of this medicine (listed in section 6).
- octylphenol ethoxylate, a trace residue from the manufacturing process.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Supemtek TIVr.

As with all vaccines, Supemtek TIVr may not fully protect all persons who are vaccinated.

Before receiving the vaccine, tell your doctor, nurse or pharmacist if:

- you have a **short-term illness** with fever. Vaccination may need to be delayed until your fever has gone.
- you have a **weakened immune system** (immunodeficiency or you are taking medicines that affect the immune system such as cancer medicine (chemotherapy) or corticosteroid medicines).
- you have a b**leeding problem** or **bruise easily**.
- you have **fainted** with an injection before. Fainting can happen after, or even before an injection.

If any of the above apply to you (or you are not sure) talk to your doctor, pharmacist or nurse before receiving Supemtek TIVr.

Other medicines and Supemtek TIVr

Tell your doctor or nurse if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription or if you have recently received any other vaccine.

Supemtek TIVr may be given at the same time as other vaccines by using separate limbs.

Pregnancy and breast-feeding

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 using this vaccine. Your doctor or pharmacist will help you to decide if you should receive Supemtek TIVr.

Driving and using machines

Supemtek TIVr has no or negligible effect on your ability to drive and use machines. However, use caution when driving or using machines if your ability to react is reduced due to some of the effects mentioned under section 4 (Possible side effects).

Supemtek TIVr contains sodium and polysorbate 20

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

This medicine contains 0.0275 mg of polysorbate 20 (E432) in each 0.5 mL dose. Polysorbates may cause allergic reactions.

3. How Supemtek TIVr is given

Supemtek TIVr is given to you by your doctor, nurse or pharmacist as an injection into the muscle at the top of the upper arm (deltoid muscle).

Adults and children from 9 years of age and older:

One dose of 0.5 mL.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with recombinant influenza vaccines (Supemtek and Supemtek TIVr):

Very serious side effects

Contact your doctor or healthcare professional **immediately** or go to the nearest hospital emergency room right away if you have a severe allergic reaction (anaphylactic reaction). It can be life-threatening.

Symptoms include:

- difficulty breathing, shortness of breath
- swelling of the face, lips, throat or tongue
- cold, clammy skin
- palpitations
- feeling dizzy, feeling weak, fainting
- rash or itching

Serious side effects

Contact your doctor or healthcare professional **immediately** or go to the nearest hospital emergency room right away if you experience any of the following side effects:

- stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (Guillain-Barré syndrome).

Other side effects

Very common (may affect more than 1 in 10 people):

- headache
- feeling tired (fatigue)
- muscle pain
- joint pain
- tenderness at the injection site
- pain at the injection site

Muscle pain and joint pain are common in adults aged 50 years and older.

Common (may affect up to 1 in 10 people):

- feeling sick (nausea)
- redness, swelling, hardening around the area and bruising where the vaccine is injected
- fever, shivering/chills

Fever is rare in adults aged 50 years and older.

Bruising is reported in children/adolescents 9 to 17 years of age.

Uncommon (may affect up to 1 in 100 people):

- asthma
- cough
- mouth and throat pain
- diarrhoea, vomiting, abdominal discomfort and decreased appetite
- itching
- skin irritation
- rash
- flu-like symptoms
- itching where the vaccine is injected

Itching is rare in adults aged 50 years and older.

Skin irritation and rash have not been reported in adults aged 50 years and over.

Flu-like symptoms has not been reported in adults aged 18-49 years.

Vomiting, decreased appetite, abdominal discomfort and asthma has not been reported in adults 18 years and older.

Rare (may affect up to 1 in 1000 people):

- feeling dizzy
- hives

Feeling dizzy and hives have not been reported in adults aged 18-49 years.

Feeling dizzy is uncommon in children/adolescents 9 to 17 years of age.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Supemtek TIVr

Keep this vaccine out of the sight and reach of children.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the pre-filled syringe in the outer carton in order to protect from light.

Do not use this vaccine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Supemtek TIVr contains

One dose (0.5 mL) contains:

The active substances are influenza virus haemagglutinin (HA) proteins, of the following strains*:

A/Wisconsin/67/2022 (H1N1)pdm09-like strain
(A/West Virginia/30/2022) . . . . . 45 micrograms HA

A/District of Columbia/27/2023 (H3N2)-like strain
(A/District of Columbia/27/2023) . . . . . 45 micrograms HA

B/Austria/1359417/2021-like strain
(B/Austria/1359417/2021) . . . . . 45 micrograms HA

* produced by recombinant DNA technology using a baculovirus expression system in a continuous insect cell line that is derived from Sf9 cells of the fall armyworm, *Spodoptera frugiperda*.

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

The other ingredients are: polysorbate 20 (E432), sodium chloride, sodium phosphate monobasic, sodium phosphate dibasic, water for injections (see Section 2).

What Supemtek TIVr looks like and contents of the pack

Supemtek TIVr is a solution for injection in a pre-filled syringe (injection) (ready to use syringe).

Supemtek TIVr is a clear and colourless solution.

Each pre-filled syringe contains a single dose (0.5 mL) of solution for injection.

Supemtek TIVr is available in packs containing 1, 5 or 10 pre-filled syringes without needle or with separate needle. Not all pack sizes may be marketed.

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This leaflet was last revised in 01/2026.

The following information is intended for healthcare professionals only:

Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

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