Supemtek Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture)		Package Insert - 10x1 Syringe d in cell culture) United Kingdom
Dieline Adimmune-P041497 Insert Dimensions: Final Fold Dimensions:	Package Insert to scale. 91 x 420 mm 91 x 105 mm	Part Number: CP-0000Product ID: 529File Name: 529 PI CP-0000 V2 10x1 UK 03Feb25Date: 03 February 2025Initials: HFVersion: 2
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Package Leaflet – Information for the User Supertex Solution for injection in pre-filled syringe

Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture) This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side

- affects you may get. See the end of section 4 for how to report side effects. 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.

What is in this leaflet:

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

1. What Supemtek is and what it is used for

Supemtek is a vaccine for adults who are 18 years of age and older. This vaccine helps to protect you against flu (influenza). Supemtek is egg-free because of the technology used to produce it.

How Supemtek works

When a person is given Supemtek, 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 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

Do not use Supemtek 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 residual from the manufacturing process. Warnings and precautions

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

As with all vaccines, Supemtek 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

(chemotherapy) or corticosteroid medicines). • you have a bleeding problem or bruise easily. • you have **fainted** with an injection before. Fainting can happen after, or e before an injection.

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

· you have a weakened immune system (immunodeficiency or you

taking medicines that affect the immune system such as cancer med

Other medicines and Supemtek

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

Supemtek may be given at the same time as other vaccines by using separate lin Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are plan to have a baby, ask your doctor or pharmacist for advice before using this vace Your doctor or pharmacist will help you to decide if you should receive Supemt Driving and using machines

Supemtek has no or negligible effect on your ability to drive and use machine Supemtek contains sodium

This vaccine contains less than 1 mmol sodium (23 mg) per dose, this means it's essentially 'sodium free'.

headache

• muscle pain and joint pain

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 where the vaccine is injected fever, shivering
- Fever is rare in adults aged 50 years and older.

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

- diarrhoea
- itching, skin irritation, rash
- flu-like symptoms
- cough, mouth and throat pain
- 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 older. Flu-like symptoms has not been reported in adults aged 18-49 years.

- 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. Not known (cannot be estimated from the available data):

• neurological disorders that may result in 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).

Reporting of side effects

until vour fever has gone.

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 national reporting system (see details below). By reporting side effects, you can help provide more information on the safety of this medicine. United Kingdom

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.

5. How to store Supemtek

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.

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 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 microgram Å/Darwin/6/2021 (H3N2)-like strain B/Austria/1359417/2021-like strain B/Phuket/3073/2013-like strain 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 armyw Spodoptera frugiperda. This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2023/2024 season. The other ingredients are: polysorbate 20 (E432), sodium chloride, sod phosphate monobasic, sodium phosphate dibasic, water for injections. What Supemtek looks like and contents of the pack Supemtek is a solution for injection in a pre-filled syringe (ready to use syringe). Supemtek is a clear and colourless solution.

A single syringe contains 0.5 mL of solution for injection.

Supemtek is available in packs containing 1, 5 or 10 pre-filled syringes without prior to administration. In the event of any foreign particulate matter and/or needle or with separate needle. Not all pack sizes may be marketed. variation of physical aspect being observed, do not administer the vaccine.

are	3. How Supemtek is given	
icine	Supemtek 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 from 18 years of age and older:	
even	One dose of 0.5 mL.	
	4. Possible side effects	
acist	Like all medicines, this medicine can cause side effects, although not everybody gets them.	
	Severe allergic reactions	
any	Contact your doctor or healthcare professional immediately or go to the nearest	
you	hospital emergency room right away if you have an allergic reaction. It can be	
	life-threatening.	
nbs.	Symptoms include:	
	 difficulty breathing, shortness of breath 	
ning	 swelling of the face, lips, throat or tongue 	
cine.	cold, clammy skin	
tek.	palpitations	
_	feeling dizzy, feeling weak, fainting	
S.	 rash or itching The following side effects have been reported with Concentration 	
that	The following side effects have been reported with Supemtek: Other side effects	
liidl		
	 Very common (may affect more than 1 in 10 people): pain at the injection site 	
	 feeling tired (fatigue) 	

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This leaflet was last revised in 02/2025.

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

