Supemtek ▼ (Quadrivalent Influenza Vaccine, recombinant prepared in cell-culture), QIVr, is now included in the 2022/23 season guidance for all eligible adult cohorts[1]

2022/23 flu season JCVI advice

The Joint Committee on Vaccination and Immunisation (JCVI) **'Statement on Influenza Vaccines for 2022/23'** for adults is summarised below:[1]

"For vaccination of those aged **65 years and over**, JCVI advises the use of the following vaccines:

- Adjuvanted quadrivalent inactivated influenza vaccine (aQIV)
- High-dose quadrivalent inactivated influenza vaccine (QIV-HD)
- Quadrivalent recombinant influenza vaccine (QIVr)"

"For vaccination of adults **aged 18 to less than 65 years of age in an at-risk group**, JCVI advises the use of the following vaccines:

- Quadrivalent influenza cell-culture vaccine (QIVc)
- Quadrivalent recombinant influenza vaccine (QIVr)

The quadrivalent influenza egg-culture vaccine (QIVe) can also be considered for use in this age group if other options are not available."

There is a limited amount of data from the use of Supemtek in pregnant women. One animal study performed with trivalent recombinant influenza vaccine did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development, or early post-natal development. An assessment of the risks and benefits should be performed by a healthcare professional before administering Supemtek to a pregnant woman.[2]

What is Supemtek (QIVr)?

Supemtek is indicated for active immunisation for the prevention of influenza disease in adults.[2]

Supemtek is the first recombinant influenza vaccine in Europe. It is manufactured to offer an exact genetic match to the World Health Organization (WHO)-predicted viral strains haemagglutinin antigen.[2,3]

Supemtek is available in packs of 10 single dose pre-filled syringes, at the basic NHS cost of £220.00.

What data supports the use of Supemtek (QIVr)?

Efficacy in adults aged over 50 years

Supemtek demonstrated 30% greater relative efficacy (1% absolute efficacy) versus standard-dose QIVe, in preventing confirmed cases of influenza-like illness in adults aged 50 years and over, with respective influenza attack rates of 2.2% (Supemtek) vs 3.2% (QIVe).±[3]

±As measured by relative vaccine efficacy (rVE) in adults aged 50+ years, randomised 1:1 to receive single dose of Supemtek (n=4,303) or QIVe (n=4,301) during the 2014/15 influenza season (95% CI 10–47; P=0.006). Influenza attack rates were 2.2.% and 3.2% for Supemtek and QIVe, respectively. The lower bound (LB) of the 95% confidence interval met the pre-specified, exploratory criterion for superior rVE LB >9%. Primary endpoint: rVE against reverse transcription polymerase chain reaction-confirmed, protocol-defined, influenza-like illness caused by an influenza strain starting 14 days or more after vaccination.[3]

Immunogenicity in adults aged 18–49 years

Comparison of immunogenicity with Supemtek or standard-dose QIVe during the 2014/15 influenza season was tested according to co-primary endpoints, geometric mean antibody titres (GMT) (Table 1) and seroconversion rates (SCRs) at Day 28, across influenza strains in a randomised, controlled trial of 1,350 adults.[2,4]

Supemtek responses to three of the four influenza strains (A/H1N1, A/H3N2 and B/Massachusetts) met non-inferiority criteria. Supemtek responses to B/Brisbane/60/2008 did not meet non-inferiority criteria; however, responses were low in both groups so comparisons could not be drawn.‡[4]

Antigen	Post-vaccination GMT Supemtek (n=969)	Post-vaccination GMT QIVe (n=323)	GMT ratio QIVe/ Supemtek (95% CI)
A/H1N1	493	397	0.81 (0.71, 0.92)
A/H3N2	748	377	0.50 (0.44,0.57)
B/Massachusetts	156	134	0.86 (0.74, 0.99)
B/Brisbane	43	64	1.49 (1.29, 1.71)

Table 1: Day 28 GMTs in patients aged 18–49 years.[2]

‡Non-inferiority for haemagglutination inhibition (HAI) SCRs and post-vaccination GMT ratios for each antigen were co-primary endpoints. Success in meeting GMT non-inferiority endpoint was pre-defined as an upper bound (UB) of the two-sided 95% CI of GMT QIVe/GMT Supemtek <1.5.[2]

Supemtek antigen content

Supemtek has a higher antigen content (45 µg) than QIVc and standard-dose QIVe (15 µg).[1,2]

Click here to find out more

Presentation and appearance

Supemtek comes in pre-filled syringes in packs of ten with a Luer lock adapter that can accommodate Luer lock or Luer slip needles. Needles are not included.

There are 10 patient information leaflets (PILs) per 10 pack.

Supemtek is a clear and colourless solution.[2]

Doses and administration

One dose of 0.5 mL for intramuscular injection only. The preferred site is in the deltoid muscle.[2] The vaccine must not be injected intravascularly and must not be mixed with other vaccines in the same syringe.[2]

Please note that the safety and efficacy of Supemtek have not yet been established in individuals below 18 years of age.[2]

The Supemtek PIL can be found at: **https://www.medicines.org.uk/emc/product/12761/pil**

Summary of Supemtek safety profile

The most common reactions occurring after vaccine administration were injection-site reactions (tenderness and pain) reported overall by 48% and 37% of study participants 18–49 years of age receiving Supemtek respectively.[2] In study participants aged over 50 years, injection site tenderness was reported by 34% and injection site pain reported by 19%.[2]

The severity of the reactions was mild to moderate. Onset usually occurred within the first 3 days after vaccination. All resolved without sequelae.[2]

The full side effect profile can be found in section 4.8 of the Summary of Product Characteristics, available at **https://www.medicines.org.uk/emc/product/12761**

Storage

Store in a refrigerator (2°C–8°C). Keep the pre-filled syringe in the outer carton to protect from light.[2]

Should any fridge failures or cold chain breaches occur, please contact Medical Information via email: **uk-medicalinformation@sanofi.com** or telephone: **0800 035 2525**.

Sanofi Pasteur. MAT-GB-2104402(v1.0) October 2021

Abbreviations: aQIV, adjuvanted quadrivalent influenza vaccine; CI, confidence interval; JCVI, Joint Committee on Vaccination and Immunisation; GMT, geometric mean titre; LB, lower bound; PIL, patient information leaflet; QIVc, cell-based quadrivalent influenza vaccine; QIVe, egg-based quadrivalent influenza vaccine; QIV-HD, high-dose quadrivalent influenza vaccine; QIVr, recombinant quadrivalent influenza vaccine; rVE, relative vaccine efficacy; SCR, seroconversion rate; UB, upper bound; WHO, World Health Organization.

References:

1. Joint Committee on Vaccination and Immunisation. Advice on influenza vaccines for 2022/23. https://app.box.com/s/t5ockz9bb6xw6t2mrrzb144njplimfo0/file/863135232161 [Last accessed October 2021].
2. Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture) Summary of Product Characteristics. Sanofi Pasteur [January 2021].
3. Dunkle LM, *et al. N Engl J Med*. 2017;376:2427–36.
4. Dunkle LM, *et al. J Infect Dis*. 2017;216:1219–26.

Prescribing Information: Supemtek solution for injection in pre-filled syringe ▽ Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture)
Please refer to the Summary of Product Characteristics (SPC) before prescribing. Presentation:

Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture) contains 45 micrograms of antigen (per 0.5 millilitre) from each of the four virus strains recommended by the World Health Organization for the present influenza season. It is supplied as single dose prefilled syringes each containing 0.5 millilitre of suspension for injection. **Indication:** Supemtek is indicated for active immunisation for the prevention of influenza disease in adults. Supemtek should be used in accordance with official recommendations. **Dosage and Administration:** One dose of 0.5 mL given intramuscularly. The preferred site is in the deltoid muscle. The vaccine must not be injected intravascularly and must not be mixed with other vaccines in the same syringe. *Paediatric population*: Safety and efficacy of Supemtek have not yet been established in individuals below 18 years of age. **Contraindications:** Hypersensitivity to the active substances, to any of the excipients or to any trace residuals such as octylphenol ethoxylate. **Precautions and Warnings:** Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Hypersensitivity: Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Intercurrent illness: Vaccination should be postponed in patients with acute febrile illness until the fever is resolved. Immunodeficiency: Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient to prevent influenza. Thrombocytopenia and coagulation disorders: As with all injectable vaccines, Supemtek must be administered with caution to individuals with thrombocytopaenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Syncope: Syncope can occur following or even before any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs. Protection: As with any vaccine, vaccination with Supemtek may not protect all vaccinees. Sodium content: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say is essentially "sodium free". ***Interactions*:** No interaction studies have been performed, nor data to assess the concomitant administration of Supemtek with other vaccines. If Supemtek is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites. Pregnancy: There is a limited amount of data from the use of Supemtek in pregnant women. One animal study performed with trivalent recombinant influenza vaccine did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development or early post-natal development. An assessment of the risks and benefits should be performed by a health care professional before administering Supemtek to a pregnant woman. Breast-feeding: It is not known whether Supemtek vaccine is excreted in human milk. An assessment of the risks and benefits should be performed by a health care professional before administering Supemtek to a breast-feeding woman. Fertility: No human fertility data are available. The animal study with trivalent recombinant influenza vaccine did not indicate harmful effects on female fertility. **Adverse Reactions:** *Very common (≥1/10)*: Headache, fatigue, myalgia, arthralgia, local tenderness, local pain *Common (≥1/100 to <1/10)*: Nausea, firmness / swelling, redness, fever, shivering / chills. For full details please refer to SPC.
List price: Packs of 10 single dose pre-filled syringes, basic NHS cost £220.00
Legal Category: POM
Marketing Authorisation Number: PLGB 04425/0879
Marketing Authorisation Holder: Aventis Pharma Ltd, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK (trading as Sanofi Pasteur)
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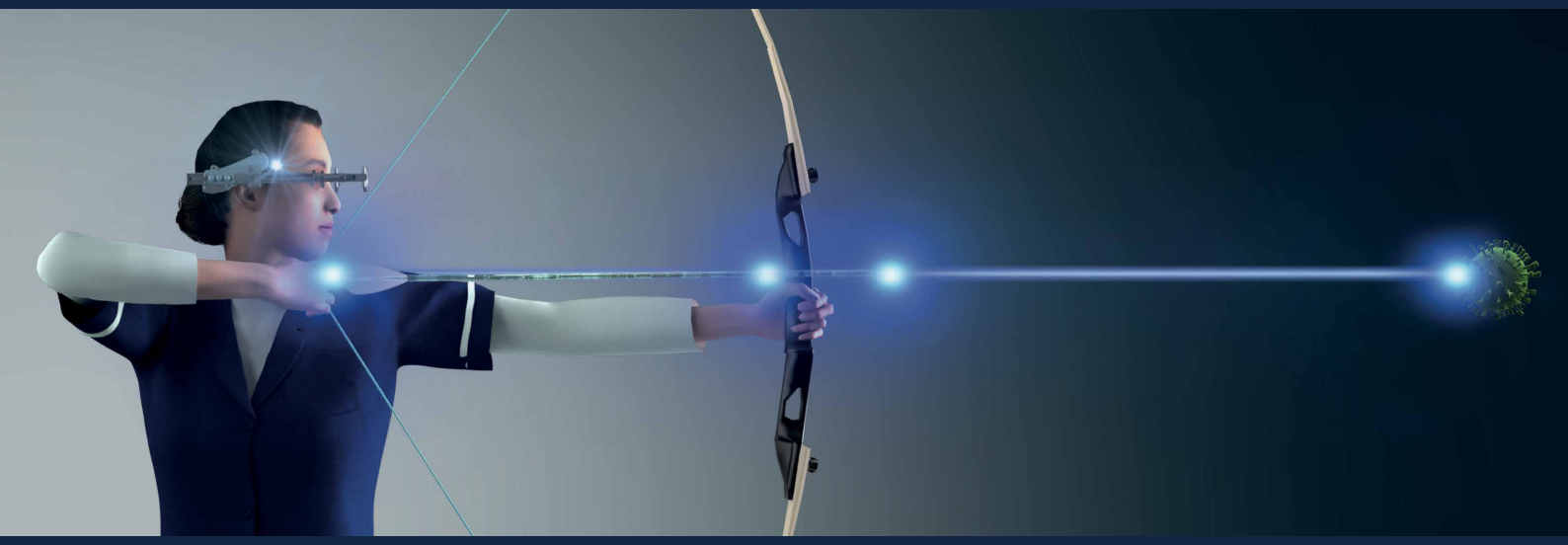
Reporting side effects

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Sanofi drug safety department on: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com



Supemtek
Quadrivalent Influenza Vaccine
(recombinant, prepared in cell culture)

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