SANOFI PASTEUR

Flublok® Quadrivalent (Influenza Vaccine), Sterile Solution for Intramuscular Injection recombinant, prepared in cell culture

This medicinal product does not have a UK marketing authorisation but has been given authorisation for temporary supply by the UK Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) for immunisation against influenza. Flublok is licensed for use in the USA by the Food and Drug Administration (FDA).[1]

This document is intended for HCPs and aims to provide an overview of the practical information needed when ordering and administering Flublok Quadrivalent influenza vaccine.

DISTRIBUTOR:

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.

In case of any questions or requests for further information, please contact the Sanofi Medical Information Department at **uk-medicalinformation@sanofi.com** or **0800 035 2525**.

REPORTING SIDE EFFECTS:

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**

INDICATED FOR:

Flublok Quadrivalent influenza vaccine is indicated for active immunisation against disease caused by influenza A subtype viruses and influenza type B viruses. Flublok Quadrivalent is approved for use in adults 18 years of age and older.[1]

THE PRODUCT:

The Flublok Quadrivalent influenza vaccine was approved in the USA by the FDA in 2016.[2] Flublok Quadrivalent has been deemed suitable for use in influenza immunisation programmes by the Joint Committee on Vaccination and Immunisation (JCVI)[3] and has been given authorisation for temporary supply by the UK DHSC and the MHRA for immunisation against flu in this year's seasonal flu programme to meet public health need for persons 18 years of age and older.[2,3]

RECOMBINANT TECHNOLOGY MANUFACTURING PLATFORM:

Flublok Quadrivalent is produced by using recombinant technology, using a baculovirus expression system in a continuous insect cell line derived from Sf9 cells of the fall army worm, *Spodoptera frugiperda*.[1]

In the production of Flublok Quadrivalent, only the haemagglutinin (HA) antigen DNA for each World Health Organisation (WHO)-recommended influenza strain is combined with host cell DNA. The host cell then produces the antigen for each of these strains. These antigens, a part of the virus that will provoke the body to develop immune protection, are then harvested for inclusion in the vaccine.[4,5]

DOSE AND ADMINISTRATION:

For intramuscular (IM) injection only (0.5 mL). One dose (0.5 mL) contains the influenza virus HA proteins, of the following strains:[1]

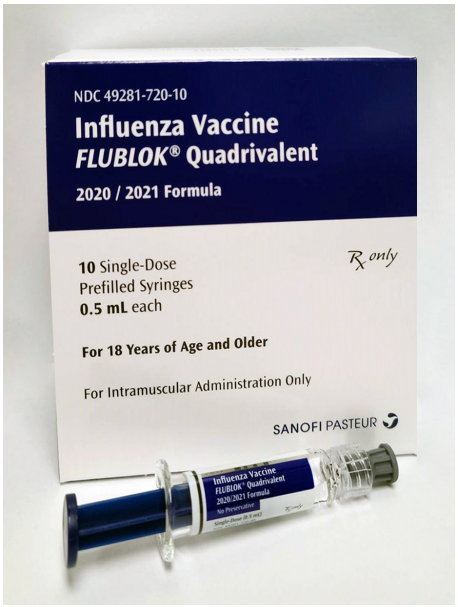
A/Hawaii/70/2019 (H1N1)	45 micrograms HA
A/Minnesota/41/2019 (an A/Hong Kong/45/2019-like virus) (H3N2)	45 micrograms HA
B/Washington/02/2019	45 micrograms HA
B/Phuket/3073/2013	45 micrograms HA

This vaccine complies with the WHO recommendation (northern hemisphere) and US and EU recommendations for the 2020/21 season.[1]

SUPPLIED AS:

Flublok Quadrivalent is a solution for injection in a pre-filled syringe (ready to use syringe) without needle. Flublok Quadrivalent is a clear and colourless solution. A single syringe contains 0.5 mL of solution for IM injection. Flublok Quadrivalent is available in packs containing 10 pre-filled syringes. The syringe has a Luer lock adapter that can accommodate Luer lock or Luer slip needles. Needles are not included. Note that the product information leaflets (PIL) will be supplied as poly-wrapped packs of 10 leaflets.[1] The PIL may also be accessed here: **https://www.sanofipasteur.co.uk/-/media/EMS/Conditions/Vaccines/Brands/OnePortal-IE/PDF/sp-flu-pil**.

FLUBLOK QUADRIVALENT PACKAGING:



STORAGE AND HANDLING:

- Store refrigerated between 2°C and 8°C. Do not freeze; discard product if it has been frozen.[1]
- Protect syringes from light.[1]
- Do not use after expiration date as shown on the label.[1]

CONTRAINDICATIONS:

Flublok Quadrivalent is contraindicated in individuals with known severe allergic reactions (e.g. anaphylaxis) to any component of the vaccine.[1]
The vaccine components are influenza HA antigens, polysorbate 20 (E432), sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic dodecahydrate and water for injection.[1]

ADVERSE REACTIONS:

Adverse events (AEs) reported as 'very common' (affecting more than 1 in 10 people) include pain at the injection site, fatigue, headache, muscle pain and joint pain. In adults aged 50 years and older, muscle pain and joint pain are reported as 'common'. Other common side effects (affecting up to 1 in 10 people) may include nausea, redness, swelling, hardening around the injection site, fever, and shivering. Fever, however, is 'rare' (affecting up to 1 in 1000 people) in adults aged 50 years and older.[1]
For further information and the full list of AEs, please refer to the PIL, which can be accessed here **https://www.sanofipasteur.co.uk/-/media/EMS/Conditions/Vaccines/Brands/OnePortal-IE/PDF/sp-flu-pil**.

WARNINGS AND PRECAUTIONS:

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Flublok Quadrivalent. Please see Flublok Quadrivalent's PIL for more information.[1]

IMPORTANT SAFETY INFORMATION FOR FLUBLOK QUADRIVALENT:

For further safety information about Flublok Quadrivalent, please refer to the PIL, which can be accessed here:
https://www.sanofipasteur.co.uk/-/media/EMS/Conditions/Vaccines/Brands/OnePortal-IE/PDF/sp-flu-pil.

TO ORDER FLUBLOK QUADRIVALENT:

You can order Flublok Quadrivalent through your Vaxishop account at **www.vaxishop.co.uk**.

REFERENCES:

1. Flublok® Quadrivalent (influenza vaccine), sterile solution for intramuscular injection, recombinant, prepared in cell culture. PIL. November 2020.
2. Gov.uk. Flublok vaccine given authorisation for temporary supply in the UK to meet public health need. Available at: https://www.gov.uk/government/news/flublok-vaccine-given-authorisation-for-temporary-supply-in-the-uk-to-meet-public-health-need. (Last accessed November 2020).
3. Joint Committee on Vaccination and Immunisation. Minutes of meeting held on 3rd June 2020. Available at: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/691486511316. (Last accessed November 2020).
4. Centers for Disease Control and Prevention. How influenza (flu) vaccines are made. Available at: https://www.cdc.gov/flu/prevent/how-fluvaccine-made.htm#recombinant (Last accessed November 2020).
5. Harding AT and Heaton NS. *Vaccines*. 2018;6(2):19.