

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Severe allergic reactions

Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you have an allergic 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

The following side effects have been reported with Flublok Quadrivalent:

Other side effects

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

- pain at the injection site
- feeling tired (fatigue)
- 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):

- 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):

- hives

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

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 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 Flublok Quadrivalent

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 Flublok Quadrivalent contains

One dose (0.5 mL) contains:

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

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

* 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 US and EU recommendations for the 2020/2021 season.

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

Flublok Quadrivalent contains no egg proteins, antibiotics, or preservatives. The single-dose, pre-filled syringes contain no natural rubber latex.

What Flublok Quadrivalent looks like and contents of the pack

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

Flublok Quadrivalent is a clear and colourless solution.

A single syringe contains 0.5 mL of solution for injection.

Flublok Quadrivalent 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.

Manufacturer

Protein Sciences Corporation (Meriden, CT)
U.S. license No. 1795
USA

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This leaflet was prepared 10/2020

The UK Public Assessment Report for Flublok is available at: <https://products.mhra.gov.uk/search/?search=flublok>