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

SANOFI

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 and the Medicines & Healthcare products Regulatory Agency for immunisation against influenza. Flublok is licensed for use in the USA by the Food and Drug Administration.

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

Reporting of Side Effects

As with any new medicine in the UK this product will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects 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 Flublok Quadrivalent is and what it is used for
2. What you need to know before you receive Flublok Quadrivalent
3. How Flublok Quadrivalent is given
4. Possible side effects
5. How to store Flublok Quadrivalent
6. Contents of the pack and other information

1. What Flublok Quadrivalent is and what it is used for

Flublok Quadrivalent is a vaccine for adults who are 18 years of age and older. This vaccine is indicated for active immunisation against flu (influenza) caused by influenza A subtype viruses and type B viruses contained in the vaccine.

How Flublok Quadrivalent works
When a person is given Flublok Quadrivalent, the body's natural defense (the immune system) produces protection against the influenza virus. None of the ingredients in the vaccine can cause flu.
As with all vaccines, Flublok Quadrivalent 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 Flublok Quadrivalent

Do not use
Flublok Quadrivalent if you are allergic to the active ingredients or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before receiving Flublok Quadrivalent. As with all vaccines, Flublok Quadrivalent 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 fainted with an injection before. Fainting can happen after, or even before an injection.

If you have developed Guillain Barré Syndrome within 6 weeks of receiving a previous influenza vaccine, your doctor will decide if you should be given this vaccine.

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

Other medicines and Flublok Quadrivalent
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.
Data evaluating the use of Flublok Quadrivalent at the same time as other vaccines are not available.

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 Flublok Quadrivalent.

Driving and using machines
Flublok Quadrivalent has no or little effect on your ability to drive and use machines.

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

3. How Flublok Quadrivalent is given

Flublok Quadrivalent 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:
One dose of 0.5 mL.

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 you 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, prefilled 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
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USA

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