

**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.