

Flublok vaccine given authorisation for temporary supply in the UK to meet public health need

Flublok vaccine

Flublok is a flu (influenza) vaccine for adults who are 18 years of age and older. It will be used as part of the UK's 2020/21 seasonal flu programme from December.

Flublok is made by Sanofi and is licensed for use in the USA by the Food and Drug Administration (FDA). It has been used there since 2016 and has been distributed to over 9 million people. The FDA considers the vaccine safe and acceptable for use.

Flublok has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency (MHRA) for immunisation against flu in this year's seasonal flu programme to meet public health need.

Scientific assessment

The MHRA assessed the available scientific evidence for Flublok relating to its safety, quality and effectiveness.

Their assessment was based in part on evidence from another closely related Sanofi flu vaccine, Supemtek. This was recommended for approval by the European Medicines Agency in September 2020.

The MHRA assessment showed the two products are fundamentally similar on the basis of a review of the manufacture, control, quality, non-clinical and clinical evaluation.

The regulator also sought advice from the government's independent expert scientific advisory body – the [Commission on Human Medicines](#) (CHM). The CHM agreed with the MHRA's assessment and concluded that Flublok protects against flu and meets high standards of safety and quality.

Advice for the general public

Flu can spread very fast and can have serious consequences. Having a flu vaccine can protect you and helps reduce transmission to others.

Your doctor can recommend the best time to be vaccinated.

Please read the patient information leaflet (PIL) carefully before you get a flu vaccine.

Like all medicines and vaccines, Flublok can cause side effects, although not everyone gets them.

If you get any side effects, even if suspected, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the PIL.

You can also report side effects directly via the national reporting system run by the MHRA known as the [Yellow Card Scheme](#). Or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of medicines.