

FDA Approves Flublok® Quadrivalent Influenza Vaccine

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Meriden, CT—Protein Sciences Corporation announced today that the FDA has approved its quadrivalent formulation of Flublok® influenza vaccine. Flublok Quadrivalent protects against 4 strains of influenza, 3 of the same strains found in trivalent Flublok plus an additional B strain. Significantly, Flublok Quadrivalent is the first and only high antigen content quadrivalent flu vaccine approved by FDA. It contains 3x more active ingredient than all other quadrivalent vaccines, making it a great choice for seniors and those with compromised immune systems, among others. In a clinical study of 9,000 adults 50 years of age and older, people who received Flublok Quadrivalent were over 40% less likely to get cell-culture confirmed influenza than those that received a leading egg-produced quadrivalent flu vaccine. These results are relevant for trivalent Flublok, as the H3N2 component of the vaccine that is shared between trivalent and Flublok Quadrivalent predominately contributed to the improved efficacy. This data can be found in the updated Package Insert for trivalent Flublok that can be downloaded here: https://www.flublok.com/media/1062/flublok-trivalent-pi.pdf.

Flublok Quadrivalent is approved for adults 18 and older and will be available in pre-filled syringes beginning in 2017. Flublok Quadrivalent has the same purity advantages as trivalent Flublok, containing pure protein made without infectious influenza virus, antibiotics, eggs, thimerosal, preservatives, gelatin or latex. Trivalent Flublok is available at hundreds of pharmacies across the United States, as listed on the Flublok Finder here: https://www.flublok.com/get-flublok/flublok-finder/.

"The U.S. has been trending toward the use of quadrivalent flu vaccines in recent years," said Manon Cox, President and CEO of Protein Sciences Corporation. "We are pleased to bring Flublok Quadrivalent to market to give consumers additional options, especially seniors who have no other high antigen content quadrivalent vaccine available to them. We are looking forward to launching the vaccine next year and, in the meantime, continuing to make trivalent Flublok available this year."

To find the closest location to you offering Flublok, visit our <u>Flublok Finder</u> today. If you still have difficulty finding a location close to you, please contact Protein Sciences directly by calling us at the phone number listed below.

For more information about Flublok, please visit www.flublok.com.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

About Flublok

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was initially approved by the U.S. FDA in January 2013. FDA expanded its approval in October 2014 to include everyone over 18 years and approved a nine-month shelf life in June 2016. Flublok is also licensed for sale in Mexico and licensure in additional countries, including Japan, is expected in the near future. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus, antibiotics or harsh chemicals in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, which contains mercury), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein) and was shown to have better efficacy in a 2014/15 post-marketing study.*Flublok is an accurate copy of the virus coat and is not subject to the egg-adapted mutations that can be associated with low vaccine effectiveness (see Skowronski et al. (2014) PLOS ONE 9(3), e92153).

Healthcare professionals wishing to order Flublok should contact one of the following distributors:

- Protein Sciences Corporation: 203-686-0800 www.flublok.com
- FFF Enterprises: 800-843-7477 www.myfluvaccine.com
- Cardinal Health: 866-677-4844 www.cardinalhealth.com/flu
- McKesson: 877-MCK-4FLU mms.mckesson.com
- Moore Medical: 800-234-1464 www.mooremedical.com/flu
- Henry Schein: 1-800-772-4346 <u>www.henryschein.com</u>

Learn more at www.proteinsciences.com and www.flublok.com.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur. Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine. Vaccination with Flublok may not protect all individuals. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

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^{*}Flublok demonstrated a higher antibody response to the A strains in two field trials in adults ≥50 years old. The B strain antibody responses were comparable to traditional trivalent and quadrivalent vaccines.