B-strain mismatch

A mismatch between the predicted and actual circulating B strain has occurred in more than half of Canadian influenza seasons since 2001.* Learn about the FLULAVAL® TETRA 4-strain influenza vaccine from our self-directed learning module

Indication and Clinical Use:

FLULAVAL® TETRA is a quadrivalent vaccine indicated for active immunization of adults and children from 6 months of age for the prevention of influenza disease caused by influenza virus types A and B contained in the vaccine.†

A decrease in influenza disease following vaccination with FLULAVAL® TETRA has been demonstrated in a controlled clinical trial in children 3-6 years of age. The indication in children aged 6-35 months is based on immune response elicited following vaccination, efficacy of the vaccine in this age group has not been established.

Containments:

• FLULAVAL® TETRA should not be administered to subjects with known hypersensitivity to egg proteins or prior administration of any influenza vaccine produced in eggs or to any component of the vaccine.

Most Serious Warnings and Precautions:

• Anaphylaxis: As with all vaccines, vaccine reactions, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

• Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

• As with any vaccine, a protective immune response may not be elicited in all vaccinees.

• In children 3–17 years of age, the most common (≥10%) solicited local reactions were pain (65%), injection site bruising (29.1%) and redness (22.5%) and loss of appetite (17%). In children 5–17 years of age, the most common (≥10%) systemic adverse events were irritability (29.1%) and loss of appetite (22.5%). In children 3–4 years of age, the most common (≥10%) solicited local reactions were redness (22.5%), pain (22.5%) and swelling (22.5%) and loss of appetite (17%). In children 5–17 years of age, the most common (≥10%) systemic adverse events were irritability (29.1%), fatigue (22.5%), headache (22.5%), arthralgia (13%) and gastrointestinal symptoms (19%).

• An adequate immune response may not be elicited in patients receiving immunosuppressive treatment or patients with immunodeficiency.

• Soreness and redness at the injection site may occur and may last for up to two days. Prophylactic acetaminophen may decrease the frequency of pain at the injection site.

• If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLULAVAL® TETRA should be based on the careful consideration of the potential benefits and risks.

• As with other vaccines administered intramuscularly, FLULAVAL® TETRA should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.

• As with other vaccines, vaccination with FLULAVAL® TETRA should be postponed in subjects suffering from an acute severe febrile illness.

• The 2016–2017 Northern Hemisphere influenza virus strains are: A/California/7/2009 (H1N1)pdm09-like virus; A/Hong Kong/4801/2014 (H3N2)-like virus; and B/Yamagata/16/2014-like (Victoria lineage).†

• The 2017–2018 Northern Hemisphere influenza virus strains are: A/Hong Kong/4802/2014 (H1N1)pdm09-like virus; A/Phuket/3073/2013 (H3N2)-like virus; and B/Victoria/362/2016-like (Yamagata lineage).†

• FLULAVAL® TETRA is not effective against all possible strains of influenza virus. FLULAVAL® TETRA is intended to provide protection against influenza A(H3N2) and influenza B(Yamagata and Victoria lineages) strains.

Dosage and Method of Administration:

• FLULAVAL® TETRA should be administered as a single 0.5 mL intramuscular injection. It is recommended to use a 1 mL syringe equipped with a needle gauge not larger than 23-G.

• FLULAVAL® TETRA should be administered intramuscularly. Vaccination should be carried out by intramuscular injection preferably into the deltoid muscle or antecubital (high) (depending on the muscle mass).

• Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection.

• FLULAVAL® TETRA is a quadrivalent vaccine indicated for active immunization of adults and children

• For More Information

Please visit the Product Monograph at http://sgc.com/products/en/2015383148/1235397-flulaval-tetra-pgweb.html for important information relating to additional cautions, warnings, and precautions, which have not been discussed in this Product Monograph.

For technical questions, please call 1-800-387-7374.

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