Influenza Virus Vaccine, Trivalent, Types A and B (Purified Subvirion) is a sterile aqueous suspension for intramuscular injection.

**DESCRIPTION**

FluShield® Influenza Virus Vaccine, Trivalent, Types A and B (Purified Subvirion) is a sterile aqueous suspension for intramuscular injection.

**Target Groups for Vaccination**

- **Groups at increased risk for influenza-related complications:**
  - Persons aged 50-64 years
  - Persons aged ≥65 years
  - Persons who can transmit influenza to persons at high risk
  - Pregnant women
  - Persons aged 5-23 years who have chronic medical conditions
  - Persons aged >23 years with hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]).

**Clinical Pharmacology**

- Influenza virus vaccine contains purified, killed influenza virus antigens prepared from influenza virus strains isolated in the current season. The vaccine contains the strains recommended by the World Health Organization (WHO) and the Advisory Committee on Immunization Practices (ACIP) for the 2001-2002 season.

**CONTRAINDICATIONS**

- Influenza virus vaccine is contraindicated for immunocompromised persons. The vaccine should not be given to persons with a past history of Guillain-Barré syndrome (GBS) (see PRECAUTIONS - Pregnancy) or to persons with a past history of GBS.

**Precautions**

- Persons with a history of Guillain-Barré syndrome (GBS) should not be given influenza virus vaccine (see CONTRAINDICATIONS).

**Warnings**

- Patients with impaired immune responsiveness, whether due to the use of immunosuppressive therapy (including irradiation, large amounts of corticosteroids, antithymocyte antibodies, and cytotoxic agents), a genetic defect, HIV infection, or any other underlying disease, should receive the vaccine only if the benefits outweigh the risks.

**Adverse Reactions**

- Local reactions following the intramuscular administration of influenza vaccine are generally minimal and include pain, tenderness, and redness at the injection site.

**Overdosage**

- There is no established treatment for influenza. If complications occur after administration of influenza vaccine, concurrent medical therapy should be initiated.
The benefits of preventing influenza-related complications versus the theoretical risk of fetal harm should be considered. Protocols have been published for stabilizing influenza vaccination in pregnant women to provide maximum protection.

Pregnancy

Pregnancy Category C:
Pregnancy FluShield has not been evaluated for its carcinogenic or mutagenic potential or for impairment of fertility.

Carcinogenesis, Mutagenesis, Impairment of Fertility
As with other intramuscular injections, this product should be given with caution to a person on anticoagulant therapy. Vaccination of individuals on anticoagulant therapy has not been studied specifically. Other systemic events that have been reported include: arthralgia, asthenia, chills, dizziness, headache, fever, joint pain, lymphadenopathy, pruritus, rash, nausea, vomiting, diarrhea, and pharyngitis. Recent placebo-controlled studies have shown that immunization of children aged 6 months to 18 years with a live attenuated influenza vaccine (LAIV) receipt among children in certain high risk conditions, such as those with chronic conditions including asthma, diabetes, heart disease, hemoglobinopathies, or immunocompromise, may be helpful. Among the frail elderly, vaccination may decrease hospitalization for pneumonia and influenza, and death. Vaccination also serves to decrease the impact of influenza among residents.

Pediatric Use
The safety and effectiveness of influenza vaccine in pediatric patients 6 months of age or older, including those with medical conditions, has not been studied sufficiently to establish the benefits versus risks for specific conditions or diseases.

Information for Patients
Informed consent is required for patients who are 18 years of age or older. Had a history of Guillain-Barré Syndrome or other autoimmune conditions, and who are pregnant. Vaccinations are contraindicated for those who are allergic to components of the vaccine (except for patients allergic to latex, which may result in anaphylaxis). Vaccinations are contraindicated for those who have had a previous anaphylactic reaction to a component of the vaccine, and who have a known history of anaphylactic shock to the vaccine, or who are allergic to the vaccine. Vaccinations are contraindicated for those who have a history of any serious adverse reaction to a previous influenza vaccination. Vaccinations are contraindicated for those who are allergic to any of the vaccine components.

Dosage and Administration
Vaccines are administered by injection into the deltoid muscle. The recommended dosage is 2-dose schedule for children aged 6 months-17 years. The second dose should be administered 4 or more weeks after the first dose. The vaccine is generally administered intramuscularly. The vaccine is well tolerated by most patients. In a study of children aged 6 months to 17 years, the most common adverse reactions were mild to moderate local injection site reactions, such as pain and redness, and flu-like reactions, such as fever, malaise, and headache. The vaccine is well tolerated by most patients. In a study of children aged 6 months to 17 years, the most common adverse reactions were mild to moderate local injection site reactions, such as pain and redness, and flu-like reactions, such as fever, malaise, and headache.

References