

**Influenza Virus Vaccine
Fluvirin[®]
2008-2009 FORMULA**

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use FLUVIRIN[®] (Influenza Virus Vaccine) safely and effectively. See full prescribing information for FLUVIRIN[®].

**FLUVIRIN[®] (Influenza Virus Vaccine)
Suspension for Intramuscular Injection
2008-2009 Formula
Initial US Approval: 1988**

INDICATIONS AND USAGE

- FLUVIRIN[®] is an inactivated influenza virus vaccine indicated for active immunization of persons 4 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine (1).
- FLUVIRIN[®] is not indicated for children less than 4 years of age because there is evidence of diminished immune response in this age group (8.4).

DOSAGE AND ADMINISTRATION

Children

- **4 to 8 years of age:** 0.5-mL dose via intramuscular injection, one or two doses. Previously unvaccinated children 4 to 8 years of age should receive two 0.5-mL doses, one on day 1 followed by another 0.5-mL injection at least 1 month later (2.2). Children 4 to 8 years of age who have been previously vaccinated with one or two doses of any influenza virus vaccine should receive only one 0.5-mL dose (2.2).
- **9 years and older:** A single 0.5-mL intramuscular injection (2.2).

Adults

- A single 0.5-mL intramuscular injection (2.2).

DOSAGE FORMS AND STRENGTHS

FLUVIRIN[®], a sterile suspension for intramuscular injection, is supplied in two presentations:

- Prefilled syringe, 0.5-mL. Thimerosal, a mercury derivative used during manufacture, is removed by subsequent purification steps to a trace amount (≤ 1 mcg mercury per 0.5-mL dose). (3, 11)
- Multidose vial, 5-mL. Contains thimerosal, a mercury derivative (25 mcg mercury per 0.5-mL dose). Thimerosal is added as a preservative. (3, 11)

Each 0.5-mL dose contains a total of 45 micrograms (mcg) of influenza virus hemagglutinin (HA) from each of the following 3 strains: A/Brisbane/59/2007 (H1N1); A/Uruguay/716/2007 (H3N2), an A/Brisbane/10/2007-like strain; and B/Florida/4/2006. (3, 11)

CONTRAINDICATIONS

- History of systemic hypersensitivity reactions to egg proteins, or any other component of FLUVIRIN[®], or life-threatening reactions to previous influenza vaccinations. (4.1, 11)

WARNINGS AND PRECAUTIONS

- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUVIRIN[®] should be based on careful consideration of the potential benefits and risks. (5.1)
- Immunocompromised persons may have a reduced immune response to FLUVIRIN[®]. (5.2)

ADVERSE REACTIONS

The most frequently reported adverse reactions are mild hypersensitivity reactions (such as rash), local reactions at the injection site, and influenza-like symptoms. (6)

To report SUSPECTED ADVERSE REACTIONS contact Novartis Vaccines at 1-800-244-7668, or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

DRUG INTERACTIONS

- Do not mix with any other vaccine in the same syringe or vial. (7.1)
- Immunosuppressive therapies may reduce immune response to FLUVIRIN[®]. (7.2)

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of FLUVIRIN[®] have not been established in pregnant women, nursing mothers or children less than 4 years of age. (8.1, 8.3, 8.4)
- Antibody responses were lower in the geriatric population than in younger subjects. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: July 2008

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

FLUVIRIN[®] is an inactivated influenza virus vaccine indicated for immunization of persons 4 years of age and older against influenza virus disease caused by influenza virus subtypes A and type B contained in the vaccine. [see DOSAGE FORMS AND STRENGTHS (3)]

FLUVIRIN[®] is not indicated for children less than 4 years of age because there is evidence of diminished immune response in this age group.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

Inspect FLUVIRIN[®] syringes and multidose vials visually for particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

Shake the syringe vigorously before administering the vaccine and shake the multidose vial preparation each time before withdrawing a dose of vaccine.

Between uses, return the multidose vial to the recommended storage conditions between 2° and 8°C (36° and 46°F). **Do not freeze.** Discard if the vaccine has been frozen.

A separate syringe and needle or a sterile disposable unit should be used for each injection to prevent transmission of infectious agents from one person to another. Needles should be disposed of properly and not recapped.

It is recommended that small syringes (0.5-mL or 1-mL) should be used to minimize any product loss.

2.2 Recommended Dose and Schedule

Children (4 to 17 years of age):

For children 4 to 8 years of age, who have not previously been vaccinated with an influenza vaccine, FLUVIRIN[®] should be given as a 0.5-mL intramuscular injection on day 1 followed by another 0.5-mL intramuscular injection at least 1 month later. If a child between the ages of 4 and 8 years does not receive a second dose of vaccine within the same season, only one dose of vaccine should be administered the following season. (15.3)

Children, 4 to 8 years of age, who have been vaccinated in preceding year(s) with one or two doses of any influenza virus vaccine should receive only one dose. (15.3)

Children over the age of 9 should receive a single 0.5-mL intramuscular injection.

The needle size may range from 7/8 to 1¼ inches, depending on the size of the child's deltoid muscle, and should be of sufficient length to penetrate the muscle tissue. The anterolateral thigh can be used, but the needle should be longer, usually 1 inch.

Adults (18 years and older):

FLUVIRIN[®] should be administered as a single 0.5-mL intramuscular injection preferably in the region of the deltoid muscle of the upper arm.

The vaccine should not be injected in the gluteal region or areas where there may be a major nerve trunk. A needle of ≥1 inch is preferred because needles <1 inch might be of insufficient length to penetrate muscle tissue in certain adults.

3 DOSAGE FORMS AND STRENGTHS

FLUVIRIN[®] is a sterile, suspension for intramuscular injection. Each 0.5-mL dose contains a total of 45 mcg hemagglutinin from the 3 influenza virus types in the vaccine. [see DESCRIPTION (11)]

FLUVIRIN[®] is available in two presentations:

- 1) Prefilled syringe, 0.5-mL. Thimerosal, a mercury derivative used during manufacture, is removed by subsequent purification steps to a trace amount (≤ 1 mcg mercury per 0.5-mL dose).
- 2) Multidose vial, 5-mL. Contains thimerosal, a mercury derivative, added as a preservative. Each 0.5-mL dose from the multidose vial contains 25 mcg mercury.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

FLUVIRIN[®] should not be administered to anyone with known systemic hypersensitivity reactions to egg proteins (eggs or egg products), or to any component of FLUVIRIN[®], or who has had a life-threatening reaction to previous influenza vaccinations.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

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

5.2 Altered Immunocompetence

If FLUVIRIN[®] is administered to immunocompromised persons, including individuals receiving immunosuppressive therapy, the expected immune response may not be obtained.

5.3 Preventing and Managing Allergic Reactions

Prior to administration of any dose of FLUVIRIN[®], the healthcare provider should review the patient's prior immunization history for possible adverse events, to determine the existence of any contraindication to immunization with FLUVIRIN[®] and to allow an assessment of benefits and risks. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.4 Limitations of Vaccine Effectiveness

Vaccination with FLUVIRIN[®] may not protect all individuals.

6 ADVERSE REACTIONS

6.1 Overall Adverse Reaction Profile

Serious allergic reactions, including anaphylactic shock, have been observed in individuals receiving FLUVIRIN[®] during postmarketing surveillance.

