

Flucelvax® (Influenza Virus Vaccine) Fact Sheet

- *Flucelvax is a new cell-culture-derived vaccine that helps protect adults, ages 18 and up, against seasonal influenza¹*
- *Cell-culture manufacturing uses a closed production process, potentially allowing for rapid scalability*

Flucelvax® (Influenza Virus Vaccine) is indicated for adults 18 years of age and above. Flucelvax is a cell-culture-derived, seasonal influenza vaccine, developed through the use of innovative technology for influenza vaccines.

Novartis Cell-Culture Technology

Novartis has expanded the platform for production of influenza virus vaccines by using MDCK™ cell-culture technology.

Flucelvax is produced through the following steps:

- **Production of seed stock:** three influenza viruses, selected by the FDA to be included in the vaccine for the coming season, are expanded to produce seed stock for vaccine production
- **Virus propagation:** MDCK cell suspensions are expanded and inoculated with the influenza viruses, which is allowed to replicate over several days
- **Virus isolation, inactivation and purification:** viruses are separated from the cell-culture via purification procedures, chemically inactivated and disrupted by detergent; finally, influenza-antigen components are extracted
- **Final formulation:** antigen components for the three influenza strains chosen for the season are combined in the final suspension

The severity of the influenza season is highly unpredictable, making vaccination the most effective way to help prevent seasonal influenza².

Safety

In seven controlled studies of Flucelvax, the rates of serious adverse events were collected for 21 days in two studies and for 6 to 9 months in five studies. Subjects were divided into three groups, one of which received Flucelvax (N=3813), the other a US licensed comparator vaccine (N=3669) and the third a placebo (N=3894). In each of these groups, the rates of all serious adverse events among adults 18 through 64 years of age were 1%. The rates of serious adverse events among adults 65 years of age and older were both 4% in groups that received Flucelvax and those that received a US licensed comparator vaccine.

The most common reactions seen in clinical studies include³:

- Pain or redness at the injection site
- Headache
- Tiredness
- Muscle aches
- Feeling unwell (malaise)

Efficacy

Flucelvax (Influenza Virus Vaccine) has been studied in multiple clinical trials, including a study of over 11,000 people, which evaluated the vaccine's safety and immune system response compared to conventional egg-based vaccines and placebo³. Clinical studies demonstrated that Flucelvax induced an immune response in healthy adults and seniors¹.

The vaccine is also approved in 28 European Union member states, as well as Norway, under the trade name of Optaflu®.

Indication and Important Safety Information

FLUCELVAX (Influenza Virus Vaccine) is indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX is approved for use in persons 18 years of age and older⁴.

Contraindication

- *Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine.*

Warnings & Precautions

- **Guillain-Barré Syndrome (GBS):** *If GBS has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX should be based on careful consideration of the potential benefits and risks.*
- **Latex:** *The tip caps of the pre-filled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals.*
- **Preventing and Managing Allergic Reactions:** *Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.*
- **Altered Immunocompetence:** *After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.*

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- **Limitations of Vaccine Effectiveness:** Vaccination with FLUCELVAX may not protect all vaccine recipients against influenza disease.

Most Common Adverse Reactions

- The most common ($\geq 10\%$) solicited adverse reactions occurring in adults 18-64 years of age within 7 days of vaccination with FLUCELVAX were pain at the injection site, erythema at the injection site, headache, fatigue, myalgia and malaise. The most common ($\geq 10\%$) solicited adverse reactions occurring in adults ≥ 65 years of age within 7 days of vaccination were erythema at the injection site, fatigue, headache and malaise.

Please see Full Prescribing Information for FLUCELVAX

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References

1. Ambrozaitis, Arvydas et al. A novel mammalian cell-culture technique for consistent production of a well-tolerated and immunogenic trivalent subunit influenza vaccine. In Vaccine. Vol 27. Issue 43. October 9, 2009: 6022–6029. Available at: <http://www.sciencedirect.com/science/article/pii/S0264410X09011177>. Accessed on July 31, 2012.
2. Centers for Disease Control and Prevention. Key facts about influenza. March 28, 2012. Available at: <http://www.cdc.gov/flu/keyfacts.htm>. Accessed on July 3, 2012.
3. Flucelvax Package Insert. October 30, 2012.
4. Flucelvax Professional Important Safety Information. Novartis Vaccines and Diagnostics. October 23, 2012.