

National Adult & Influenza Immunization Summit

Novartis Influenza Vaccines Presentation
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GMCC-397 - 2015-05-12

Objectives and Overview

- 2014 - 2015 Influenza Season: Delivery & Performance
- 2015 - 2016 Influenza Season: Projections & Offerings
- Novartis Influenza Vaccines: Company Updates
 - Transition to CSL Limited
 - Pipeline

2014 - 2015 Influenza Season: Performance

- For the 2014-2015 influenza season, Novartis completed the shipping of ~ 43 million doses of influenza vaccine
 - Delivered to all customers in full quantities
 - First US Supplier to ship for the 2014-2015 influenza season
 - Began shipments on 2 July 2014
 - Expanded production from the initial forecast to meet increased demand

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2015 - 2016 Influenza Season: Projections

- For the 2015 - 2016 Influenza Season, Novartis plans to deliver a baseline supply of 33 to 36 million doses of influenza vaccine
 - Manufacturing process is on target

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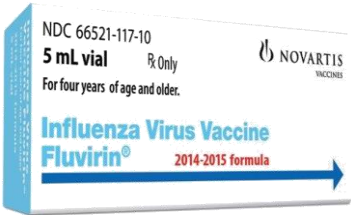
Influenza Virus Vaccine Fluvirin®

Please see Important Safety Information within this Presentation
and Full Prescribing Information Available from the Presenter




FLUVIRIN® (Influenza Virus Vaccine)

- FLUVIRIN (influenza virus vaccine) – trivalent, inactivated subunit influenza virus vaccine
- Indicated for active immunization of persons aged four years and older against influenza disease caused by influenza virus subtypes A and B included in the vaccine
- Route of administration – intramuscular
- 0.5-mL prefilled syringe – formulated with trace amount of thimerosal (≤ 1 mcg per 0.5-mL dose)
- 5-mL multidose vial – contains thimerosal as a preservative



Source: FLUVIRIN [package insert], Cambridge, MA: Novartis Vaccines and Diagnostics, Inc.; 2014.
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FLUVIRIN® (Influenza Virus Vaccine)

Important safety information

- FLUVIRIN should not be administered to anyone with known systemic hypersensitivity reactions to egg proteins (egg or egg products), or to any component of FLUVIRIN, or who has had a life-threatening reaction to previous influenza vaccinations.
- 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.
- If FLUVIRIN is administered to immunocompromised persons, including individuals receiving immunosuppressive therapy, the expected immune response may not be obtained. 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.
- The tip caps of the FLUVIRIN prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.
- Vaccination with FLUVIRIN may not protect all individuals. In clinical trials, the most common adverse events in adults were headache, fatigue, injection site reaction (pain, mass, redness, and induration), and malaise.

Source: FLUVIRIN [package insert]. Cambridge, MA: Novartis Vaccines and Diagnostics, Inc.; 2014.

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FLUCELVAX® (Influenza Vaccine)

First cell culture flu vaccine approved in the US

Cell culture technology¹⁻² allows for

- Permanent source of cells for rapid cell expansion
- Ability to grow large volumes of cells quickly and predictably
- Closed production system that does not require addition of antibiotics
- Potential scaled up production to meet unexpected surges in demand
- Diversification of supply



FLUCELVAX (influenza vaccine) has been produced in Holly Springs, North Carolina since the 2014-15 influenza season

¹ Mabrouk T et al. Dev Biol (Basel). 2002;110:125-134.

² Szymczakiewicz-Multanowska A et al. J Infect Dis. 2009;200(6):841-848.

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FLUCELVAX® (Influenza Vaccine)

- FLUCELVAX (Influenza Vaccine) is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine
- Approved for use in ages 18 and older
- Route of administration – intramuscular
- 0.5 mL Pre-filled Syringe (PFS)
- Preservative free (contains no Thimerosal)



Source: FLUVIRIN [package insert]. Cambridge, MA: Novartis Vaccines and Diagnostics, Inc.; 2014

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FLUCELVAX® (Influenza Vaccine)

Important safety information

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.
- 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

Source: FLUVIRIN [package insert], Cambridge, MA: Novartis Vaccines and Diagnostics, Inc.; 2014
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Company Update

- Transition to CSL Limited
- Pipeline



In 2015, Novartis will Divest its Vaccine Business

GlaxoSmithKline

- 22 April 2014: Novartis agreed to divest its non-influenza vaccine business (Meningococcal and Travel franchises)
- Close occurred on 2 March 2015

CSL Limited

- 26 October 2014: Novartis agreed to divest its influenza business
- On 1 March 2015 a stand alone business unit went into effect
 - Transition is expected to close at year-end
- Subject to anti-trust regulatory approvals
- Novartis remains fully committed to the influenza business during the transition period to closing, including honoring agreements with customers, research and development for influenza vaccines, and product launches.
- Both companies are determined to have a seamless transition with minimal disruption to customers and public health partners.
- "In CSL, we have found not only an owner for the influenza business that shares our commitment to protecting public health, but also a strong growth platform for the business and our associates," - Joseph Jimenez, CEO of Novartis

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Active Research and Development Pipeline

BLAs submitted to FDA:

- Adjuvanted influenza vaccine for individuals 65 years of age and older*
- Cell culture influenza vaccine for pediatric populations*
- Quadrivalent cell culture influenza vaccine*

** Candidate vaccines under current regulatory review in the United States*

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Novartis Influenza Vaccines: Summary

- Approximately 43 million doses delivered for the 2014-2015 influenza season
- Fluvirin® (*Influenza Virus Vaccine*) and Flucelvax® (*Influenza Vaccine*) to be available for the 2015-2016 influenza season
- Plans are for a baseline supply of 33-36 million doses of influenza vaccine
- Novartis remains fully committed to the influenza business during the transition period to closing, including honoring agreements with customers, research and development for influenza vaccines, and product launches.

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