



National Adult & Influenza Immunization Summit

Novartis Vaccines Presentation
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Objectives and Overview

- 2013-2014 Influenza Season: Delivery Performance
- 2014-2015 Influenza Season: Projections and Offerings

Novartis Supply Performance

- In 2013 Novartis completed the shipping of 31.6 million doses of influenza vaccine
 - Delivered to all customers in full quantities
 - Expanded production from the initial forecast of 30 million doses to assist in meeting increased demand
 - Novartis provided approximately 24% of all influenza doses in the US for the 2013-2014 influenza season
- For the 2014-2015 Influenza Season Novartis plans to bring a minimum of 30 million doses of influenza vaccine
 - Shipping expected to begin in August and continue through October
 - Manufacturing proceeding well, no issues foreseen at this point

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Formulations to be Available for the 2014-2015 Influenza Season

- FLUVIRIN® (*Influenza Virus Vaccine*)
 - 4 + years of age
 - Pre-filled Syringe (preservative-free) or Multi-Dose Vial presentations
 - Trivalent formulation
 - CPT © code 90656 (syringe) and 90658 (MDV)
- FLUCELVAX® (*Influenza Virus Vaccine*)
 - 18 + years of age
 - Pre-filled Syringe (thimerosal-free) presentation
 - Trivalent formulation
 - CPT© 90661

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FLUVIRIN® (Influenza Virus Vaccine)

Important Safety Information (1 of 2)

Indication and Usage for FLUVIRIN® (Influenza Virus Vaccine)

- Fluvirin vaccine 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.
- Fluvirin vaccine is not indicated for children less than 4 years of age because there is evidence of diminished immune response in this age group.

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 six weeks of receipt of prior influenza vaccine, the decision to give FLUVIRIN should be based on careful consideration of the potential benefits and risks.



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FLUVIRIN® (Influenza Virus Vaccine)

Important Safety Information (2 of 2)

- 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.
- Please see full Prescribing Information for more information.

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FLUCELVAX® (Influenza Virus Vaccine)

Important Safety Information (1/2)

Indication and Usage for FLUCELVAX® (Influenza Virus Vaccine)

- FLUCELVAX 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 older

Important Safety Information for FLUCELVAX

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



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FLUCELVAX® (Influenza Virus Vaccine)

Important Safety Information (2/2)

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

- Please see Full Prescribing Information for FLUCELVAX for more information



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Novartis Vaccines: Summary and Conclusions

- More than 31 million doses delivered for the 2013-2014 influenza season (24% of US production)
- Fluvirin® (*Influenza Virus Vaccine*) and Flucelvax® (*Influenza Virus Vaccine*) to be available for the 2014-2015 influenza season