



National Influenza Vaccine Summit

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GSK Influenza Vaccine Products

Fluarix[®] Influenza Virus Vaccine

- Approved for use in persons 3 years of age and older
- Available in a 0.5 mL single-dose pre-filled syringe (tip caps of the prefilled syringes may contain latex)
- Thimerosal- free
- Manufactured in Dresden, Germany

FluLaval[®] Influenza Virus Vaccine

- Approved for adults 18 years of age and older
- Available in a 5 mL multi-dose vial containing 10 doses (0.5 mL each)
- Contains thimerosal as a preservative. Each 0.5 mL dose contains 25 micrograms of mercury
- Manufactured in Quebec, Canada

FLUARIX is a vaccine indicated for active immunization for the prevention of disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUARIX is approved for use in persons 3 years of age and older.

■ **Important Safety Information**

- Do not administer FLUARIX to anyone with known severe allergic reactions to egg proteins (a vaccine component) or a life-threatening reaction to previous administration of any influenza vaccine
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUARIX should be based on careful consideration of the potential benefits and risks
- The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals
- If FLUARIX is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
- In clinical trials with FLUARIX, the most common adverse events in adults included injection site pain and redness, muscle aches, fatigue, and headache. In children 5 years to <18 years of age, the most common adverse events were similar to those in adults but also included injection site swelling. In children 3 years to <5 years of age, the most common adverse events included pain, redness, and swelling at the injection site, irritability, drowsiness, and loss of appetite. (See adverse reactions section of the Prescribing Information for FLUARIX for other potential adverse events.)
- Vaccination with FLUARIX may not result in protection in all vaccine recipients

FLULAVAL is a vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLULAVAL is approved for use in persons 18 years of age and older. This indication is based on immune response elicited by FLULAVAL, and there have been no controlled trials adequately demonstrating a decrease in influenza disease after vaccination with FLULAVAL.

■ **Important Safety Information**

- Do not administer FLULAVAL to anyone with known severe allergic reactions (eg, anaphylaxis) to any component of the vaccine including egg protein or to a previous dose of any influenza vaccination
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLULAVAL should be based on careful consideration of the potential benefits and risks
- If FLULAVAL is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
- In comparator-controlled clinical trials with FLULAVAL, adverse events included pain, redness, and swelling at the injection site; headache; fatigue; and myalgia. (See Adverse Reactions section of the Prescribing Information for FLULAVAL for other potential adverse events)
- Vaccination with FLULAVAL may not result in protection in all vaccine recipients

GSK | Market Performance in 2011

- GSK committed 35 - 37 million doses to the market in May 2011
- GSK supplied 34 million doses to the market beginning in July 2011
- GSK notified 100% of our pre-booked customers by September 15th, 2011, of their order status and delivery dates
- GSK made flu vaccine available for immediate shipping starting on September 16th

2012-2013

Vaccine Delivery Projections and Timing

- GSK estimates 25 to 28 million doses total (Fluarix and FluLaval) will be supplied to the US
- **GSK anticipates:**
 - May be able to begin shipments in as early as late July
 - Completing shipments by mid October or earlier
 - All estimates are dependent on regulatory approval and internal QA review/approval
- These are early estimates provided for planning purposes and are not a commitment to dates and amounts of vaccine

Future GSK Products

- **Four strain (quadrivalent) influenza vaccines, which will include 2 type A strains and 2 type B lineages**
 - **Fluarix manufacturing process(D-QIV)**
 - sBLA submitted based on studies conducted in children and adults
 - Proposed Indication: age 3 years and above
 - Anticipate approval by end of December 2012
 - **FluLaval manufacturing process (Q-QIV)**
 - Phase III Studies completed in adults and children
 - sBLA submission planned for 4Q2012
 - Proposed Indication: age 3 years and above



- JCR is challenging health care organizations to achieve at least 75% staff seasonal influenza coverage
- GSK is proud to support the fourth year of the Challenge for the upcoming season.
- For the 2011-2012 season 1,065 organizations registered
- GSK provided funding and other editorial support for the Flu Vaccination Challenge



