



2011-2012 National Influenza Vaccine Summit

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Influenza Franchise
GlaxoSmithKline

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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 rubber plunger 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 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 systemic hypersensitivity reactions to egg proteins (a vaccine component) or a life-threatening reaction to previous administration of any influenza vaccine
- If FLUARIX is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons
- 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 contain natural latex which may cause allergic reactions to latex sensitive individuals
- In clinical trials with FLUARIX, the most common adverse events in adults included injection site pain and redness, muscle aches, fatigue, and headache. Most adverse events in adult clinical trials were mild and self-limited. 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, loss of appetite, and fever. (See adverse reactions section of the Prescribing Information for FLUARIX for other potential adverse events.)
- Vaccination with FLUARIX may not protect 100% of susceptible individuals

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

■ **Important Safety Information**

- Do not administer FLULAVAL to anyone with known systemic hypersensitivity reactions to egg proteins (a vaccine component) or a life-threatening reaction to previous administration of any influenza vaccination
- If FLULAVAL is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons
- 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
- In clinical trials with FLULAVAL, the most common ($\geq 10\%$) local and systemic adverse events were pain, redness, and/or swelling at the injection site, headache, fatigue, myalgia, low grade fever, and malaise.
- (See Adverse Reactions section of the Prescribing Information for FLULAVAL for other potential adverse events)
- Vaccination with FLULAVAL may not protect all susceptible individuals

GSK | Market Performance in 2010

- GSK committed 35.5 M doses to the market in May 2010
- GSK delivered 31 M doses to the market beginning in July
- GSK alerted customers that 4.5 million doses would be delayed until later in the year due to:
 - 3 M doses due to FDA latex interpretation in the caps of pre-filled syringes
 - 1.5 M doses due to internal lot failures
- GSK has rectified these issues for the 2011-2012 season
 - Labels have been updated to reflect FDA's revised latex guidelines
 - We expect fewer manufacturing issues this year because of the continuous improvement process

2011-2012

Vaccine Delivery Projections and Timing

- GSK estimates 35 to 37 million doses total (Fluarix and FluLaval) will be supplied to the US
- **GSK anticipates:**
 - Beginning shipments in July
 - Completing shipments by October
 - 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

Changes for the 2011-2012 Influenza Season

- 2011 50/50 FIFO Shipping Process
 - Customers to receive 50% of their pre-booked doses by Sept 30
 - 100% pre-book fulfillment by Oct 30
 - Estimates are dependent on regulatory approval and internal QA review/approval.

- Notification Process Improvements
 - Customers will have six week visibility as to their projected delivery date
 - Customers will receive email and phone call from GSK to inform them of their estimated delivery date 1.5 weeks in advance



- JCR is challenging health care organizations to achieve 75% staff seasonal influenza coverage
- GSK is proud to support the third year of the Challenge
- For the 2010-2011 season 1,237 organizations registered
- GSK provided funding and other editorial support for the Flu Vaccination Challenge



