Most Common Adverse Reactions

• The most common (≥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 (≥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 accompanying Full Prescribing Information for FLUCELVAX.
Indication and Usage for FLUCELVAX® (Influenza 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.

Selected 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.
### Novartis—innovation adapted to influenza.

Unlike traditional flu vaccines, FLUCELVAX® is cell-culture-derived:

- Manufacturing technology uses mammalian cells instead of fertilized chicken eggs³
- Proven technology also used to produce polio, smallpox, rubella, and chickenpox vaccines³
- Made in a facility in Holly Springs, North Carolina, the first of its kind in the United States⁴

### Selected Important Safety Information

#### 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.

### Cell-culture compared to egg-based manufacturing.

<table>
<thead>
<tr>
<th>CELL-CULTURE–BASED VACCINES</th>
<th>EGG-BASED VACCINES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use readily available bank of frozen, characterized cells⁵</td>
<td>Rely on egg availability. Supply may be affected by avian flu⁷</td>
</tr>
<tr>
<td>Grow virus in closed, sterile bioreactors⁶,⁷</td>
<td>Grow virus in an open system⁵</td>
</tr>
<tr>
<td>Manufacturing technology eliminates the need for antibiotics⁸</td>
<td>Egg-based manufacturing may require use of antibiotics in the process⁵</td>
</tr>
<tr>
<td>Potential for rapid scale-up during outbreaks or pandemic⁴,⁵,⁷</td>
<td>Limit flexibility to respond to market changes or demands⁶,¹⁰</td>
</tr>
</tbody>
</table>

### Selected Important Safety Information

#### Warnings & Precautions

- **Latex:** The tip caps of the pre-filled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals.

---

Please see continued selected Important Safety Information throughout, and accompanying Full Prescribing Information for FLUCELVAX.
FLUCELVAX®—comparable efficacy.
Proven prevention of culture-confirmed influenza vs placebo2:

83.8% Of viruses matched to those in the vaccine

69.5% Of all influenza viruses

*Efficacy and immunogenicity were studied in 7 controlled international trials with more than 5,100 participants.2

FLUCELVAX—proven immunogenicity and noninferiority to Agriflu® (Influenza Virus Vaccine), an egg-based vaccine.2

- In adults aged 18 through 49 years—subjects with HI titer ≥1:40: 94%-99%, 99%, 78%-93%; subjects achieving seroconversion: 73%-78%, 59%-63%, 51%-88%, respectively (95% CI)2
- In adults aged 50 through 64 years—subjects with HI titer ≥1:40: 84%, 99%, and 87%; subjects achieving seroconversion: 57%, 66%, and 77%, respectively (95% CI)2
- Noninferiority was shown for HI antibody responses to all 3 strains for both postvaccination geometric mean titer ratios and seroconversion rates2

HI=hemagglutination inhibition; CI=confidence interval.

† Data evaluating immunogenicity for A/H1N1, A/H3N2, and B strains in 3 different studies, including 1,353 patients receiving FLUCELVAX.

FLUCELVAX—demonstrated safety.
Serious adverse events within 7 days of vaccination were:

1% among adults aged 18 through 642
- The most common (≥10%) solicited adverse reactions were pain and erythema at the injection site, headache, fatigue, myalgia, and malaise2

4% among adults aged 65 and older2
- The most common (≥10%) solicited adverse reactions were fatigue, erythema at the injection site, headache, and malaise2

Selected Important Safety Information

Warnings & Precautions
- Preventing and Managing Allergic Reactions: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.
- Syncope: Syncope (fainting) can occur in association with administration of injectable vaccines, including FLUCELVAX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope by maintaining a supine or Trendelenburg position.
- Altered Immunocompetence: After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

Please see continued selected Important Safety Information throughout, and accompanying Full Prescribing Information for FLUCELVAX.
Influenza Vaccine

RETHINK FLU

Aged 18-64 years  Aged 65 and older

<table>
<thead>
<tr>
<th>Local</th>
<th>FLUCELVAX* (n=821) (%)</th>
<th>Comparator* (n=841) (%)</th>
<th>FLUCELVAX (n=509) (%)</th>
<th>Comparator* (n=483) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>20</td>
<td>15</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Erythema</td>
<td>14</td>
<td>15</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Induration</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Swelling</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Ecchymosis</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Headache</td>
<td>12</td>
<td>11</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Fatigue</td>
<td>11</td>
<td>11</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Myalgia</td>
<td>7</td>
<td>8</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Malaise</td>
<td>11</td>
<td>11</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Chills</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>5</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Sweating</td>
<td>5</td>
<td>4</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Fever (≥38°C)</td>
<td>1</td>
<td>1</td>
<td>&lt;1</td>
<td>1</td>
</tr>
</tbody>
</table>

* Agriflu* (Influenza Virus Vaccine).

Selected Important Safety Information

Warnings & Precautions

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

This flu season, think FLUCELVAX.

- Was the first FDA-approved influenza vaccine made with modern, cell-culture technology
- Contains same flu strains as trivalent vaccines made in chicken eggs
- Manufacturing technology eliminates the need for the use of antibiotics
- Approved for adults aged 18 and older
- Offers similar efficacy and safety profiles as traditionally manufactured egg-based vaccines

Available in preservative-free prefilled syringes

Selected Important Safety Information

Most Common Adverse Reactions

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