Influenza Quadrivalent Vaccine and Pregnancy

Product Monographs
Fluzone Quadrivalent (Sanofi Pasteur) … Page 8 of 36
Special Populations - Pregnant Women
Animal reproductive studies have not been conducted with FLUZONE® Quadrivalent. It is also not known whether FLUZONE® Quadrivalent can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Data on the use of this vaccine in pregnant women are limited. FLUZONE® Quadrivalent should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits. However, there is no evidence to suggest a risk to the fetus or the pregnancy from maternal immunization with FLUZONE® Quadrivalent.

Pregnancy Registry:
Sanofi Pasteur Inc. is conducting a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with FLUZONE® Quadrivalent during pregnancy. Healthcare providers are encouraged to enroll women who receive FLUZONE® Quadrivalent during pregnancy in Sanofi Pasteur Inc.’s vaccination pregnancy registry by calling 1-888-621-1146.

Flulaval Tetra (GlaxoSmithKline) … Page 5 of 24
Special Populations - Pregnant Women
The safety of FLULAVAL® TETRA when administered to pregnant women has not been evaluated. Animal studies with FLULAVAL® TETRA do not indicate direct or indirect harmful effects with respect to reproductive and developmental toxicity. FLULAVAL® TETRA should be used during pregnancy only when clearly needed, and the possible advantages outweigh the potential risks for the foetus.

Key Messages for Quadrivalent Influenza Vaccine Use During Pregnancy
- NACI states that influenza vaccination is recommended for pregnant women.
- QIV and TIV are manufactured similarly.
- QIV and TIV ingredients are almost identical when comparing each manufacturer’s products. See attached chart.
- Product monographs are written to protect companies from possible litigation.
- ACIP does not preferentially recommend a specific formulation – trivalent or quadrivalent influenza vaccine.
- ACOG strongly supports flu vaccine in pregnant women regardless of formulation.
- Fluzone trivalent vaccine has the same statement about use for pregnant women in the product monograph.
- Companies are continually seeking more data to support their vaccines.
- Healthcare providers must use their own judgement in deciding whether or not to discuss study with client (e.g. will it increase her anxiety).
Information should be given in a positive way:
- All information to date supports safety in pregnancy.
- The benefits of influenza vaccine outweigh the risks as pregnant women are at an increased risk of serious illness due to seasonal and pandemic influenza.
- Reinforce the benefit for their baby as studies have shown that there is neonatal protection from maternal vaccination.
- If they are interested in contributing to the body of evidence that supports vaccination they are welcome to join a study.

Characteristics of Quadrivalent and Trivalent Influenza Vaccines

<table>
<thead>
<tr>
<th>Antigen Content</th>
<th>Other Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluzone Quadrivalent (QIV)</strong> Sanofi Pasteur (2015/16)</td>
<td><strong>Egg protein</strong></td>
</tr>
<tr>
<td><strong>Fluzone (TIV)</strong> Sanofi Pasteur (2014/15)</td>
<td><strong>Formaldehyde</strong></td>
</tr>
<tr>
<td><strong>Flulaval Tetra (QIV)</strong> GSK (2015/16)</td>
<td><strong>Triton X-100</strong></td>
</tr>
<tr>
<td><strong>Fluviral (TIV)</strong> GSK (2015/16)</td>
<td><strong>Sucrose</strong></td>
</tr>
</tbody>
</table>

### Antigen Content
- 15 μg HA of each strain listed below:
  - A/California/7/2009 (H1N1)pdm09-like virus
  - A/Switzerland/9715293/2013 (H3N2)-like virus
  - B/Phuket/3073/2013-like virus
  - B/Brisbane/60/2008-like virus

### Other Ingredients
- **Egg protein**
- **Formaldehyde**
- **Triton X-100**
- **Sucrose**
- Thimerosal is only use in multidose presentation.


- 15μg HA of each strain listed below:
  - A/California/7/2009 (H1N1)pdm09-like virus
  - A/Texas/50/2012 (H3N2)-like strain and
  - B/Massachusetts/2/2012-like strain.

### Note:
- **Egg protein**
- **Formaldehyde**
- **Triton X-100**
- **Sucrose**
- **Thimerosal is only use in multidose presentation.**

- 15μg HA of each strain listed below:
  - A/California/7/2009 (H1N1)pdm09-like virus
  - A/Switzerland/9715293/2013 (H3N2)-like virus
  - B/Phuket/3073/2013-like virus
  - B/Brisbane/60/2008-like virus

### Note:
- **Egg protein**
- **Formaldehyde**
- **α-tocopheryl hydrogen succinate**
- **Polysorbate 80**
- **Ethanol**
- **Sodium deoxycholate**
- **Sucrose**
- **Thimerosal is only use in multidose presentation.**

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