



## Thiomersal and Influenza vaccine – Frequently Asked Questions

### Does the influenza vaccine contain thiomersal?

Some influenza vaccines contain thiomersal as a preservative. However, these contain only trace amounts and are considered by the WHO, European Agency for the Evaluation of Medicinal Products (EMEA) and the Irish Medicines Board (IMB) to be "preservative-free". Manufacturers of some influenza vaccines use thiomersal early in the manufacturing process. The thiomersal gets diluted as the vaccine goes through the steps in processing. By the end of the manufacturing process there is not enough thiomersal left in the vaccine to act as a preservative and the vaccine is labeled "preservative-free". In these circumstances where thiomersal is used in the manufacture but results in undetectable or very low residual levels of thiomersal (i.e. below 40 nanogram of thiomersal) in the finished product there is no scientific evidence suggesting that such levels could trigger hypersensitivity reactions.

### Is it safe for children to receive an influenza vaccine that contains thiomersal?

**Yes.** There is no convincing evidence of harm caused by the small amount of thiomersal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thiomersal. The presence of thiomersal (and other preservatives) in the composition of vaccines is stated on the label and a warning regarding the risk of sensitisation in relation to thiomersal and other preservatives is included in the Summary of Product Characteristics and Package Leaflet of such products.

# Is it safe for pregnant women to receive an influenza vaccine that contains thiomersal?

**Yes.** A study of influenza vaccination examining over 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine. Case reports and limited studies indicate that pregnancy can increase the risk for serious medical complications of influenza. One American study found that out of every 10,000 women in their third trimester (last three months) of pregnancy during an average flu season, 25 will be hospitalised for influenza related complications.

Additionally, influenza-associated excess deaths among pregnant women have been documented during influenza pandemics. Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of influenza vaccine with reduced or standard thiomersal content outweighs the theoretical risk, if any, of thiomersal.

#### Links and references





## See also Thiomersal

Thiomersal and vaccines. World Health Organization

<u>EMEA public statement on thiomersal in vaccines for human use</u> – recent evidence supports safety of thiomersal containing vaccines (24 March 2004)

Thimerosal in Seasonal influenza vaccine. Centers for Disease Control. <a href="http://www.cdc.gov/FLU/ABOUT/QA/thimerosal.htm">http://www.cdc.gov/FLU/ABOUT/QA/thimerosal.htm</a>

EMEA CHMP Position Statement on Thiomersal and Implementation of the Warning Statement Relating to Sensitisation (11 January 2007)

<u>Immunization Safety Review: Vaccines and Autism.</u> Immunization Safety Review Committee, Institute of Medicine. National Academy Press Washington DC 2004.

Immunization Safety Review: Thimerosal - Containing Vaccines and Neurodevelopmental Disorders. Immunization Safety Review Committee, Institute of Medicine. Stratton K, Gable Am McCormick MC eds. National Academy Press Washington DC 2001.

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