

US Licensed Vaccines with and without Thimerosal as of January 2004

Phase Out of Thimerosal

Vaccines containing thimerosal used for recommended routine infant immunizations began to transition to mercury-free formulations in the US beginning in September 1999, when Merck released a non-thimerosal Hepatitis B vaccine. The transition to provider use of thimerosal-free infant formulations for Hepatitis B, DTaP, and Haemophilus influenzae type B vaccines **was not complete until late 2001/early 2002**. Manufacturers had completed the transition by mid 2001, but thimerosal formulations continued to move through the supply chain until administered to infants, as the FDA never issued a recall. Vaccine shelf life can be over 2 ½ years.

Several vaccines regularly administered to infants, children, and pregnant women still contain thimerosal. These vaccines are highlighted in **red type**.

Except where noted, package inserts providing thimerosal content are available at http://www.vaccinesafety.edu/package_inserts.htm

Routine Infant Vaccines

Hepatitis B

- ❖ Recombivax, by Merck: only single dose vials available for pediatric use; none contain preservatives.
- ❖ Engerix, by GlaxoSmithKline: the pediatric version has no preservatives. It contains a trace amount of mercury (less than 0.5 mcg) remaining from the manufacturing process.

Haemophilus Influenzae type B

- ❖ ActHIB, by Aventis: lyophilized, contains no preservative, no thimerosal.
- ❖ HIBTITER, by Wyeth: packaged in single dose vials. Does not contain thimerosal.
- ❖ PedvaxHIB, by Merck: does not contain thimerosal.

Diphtheria-Tetanus-Pertusis (DTaP)

- ❖ Infanrix, by GlaxoSmithKline: does not and has never contained thimerosal.
- ❖ Daptacel, by Aventis: contains 2-phenoxyethanol as a preservative; no thimerosal.
- ❖ Tripedia, by Aventis: available in single dose vials without preservative. Contains a trace from manufacturing, less than 0.3 mcg mercury per dose.*
 - ❖ The package insert says that multi-dose vials with thimerosal, at 25 mcg/Hg per dose, are also available, but the Aventis web site does not list this product for sale in the US.

Diphtheria and Tetanus Toxoid for Pediatric Use

- ❖ Sole manufacturer: Aventis: formulation is available in single dose vials without thimerosal, except for a trace of 0.3 mcg per dose.*
 - ❖ **Some single dose vials and all multidose vials still contain thimerosal.**

Inactivated Polio Vaccine (IPV)

- ❖ No formulations have contained or do contain thimerosal.

Measles-Mumps-Rubella

- ❖ Sole manufacturer in US: Merck – M-M-R II: has undetectable traces of thimerosal used in the manufacturing process.

Varicella

- ❖ Varivax, by Merck: only available in thimerosal-free single dose vials.

Pneumococcal

- ❖ Prevnar, by Wyeth: sold in single dose vials; does not contain a preservative.

Influenza

- ❖ Fluzone, by Aventis: available in thimerosal-free pre-filled syringes with a pink plunger rod for pediatric use (up to age 35 months). Contains a trace of thimerosal from manufacturing, less than 0.5 mcg Hg per pediatric dose.*
 - ❖ **Thimerosal-containing multidose vials are also marketed and are more prevalent this flu season (2003-2004).**

Comination Vaccines

- ❖ Twinrix (Hep B-HIB), by GlaxoSmithKline: contains 2-phenoxyethanol as a preservative.
 - ❖ Contains a trace of thimerosal – less than 1 mcg mercury.
- ❖ TriHibit (DTaP-HIB), by Aventis: contains no preservative, no thimerosal.
- ❖ COMVAX (Hib-Hep B), by Merck: contains no preservative, no thimerosal.
- ❖ Pediarix (DTaP-Hep B-IPV), by GlaxoSmithKline: contains 2-phenoxyethanol as a preservative; thimerosal used in manufacturing process; removed to below detectable limits, defined as <12.5 nanograms Hg per dose.

Non-Routine Vaccines (Special Populations, Children or Adults)

Hepatitis A

- ❖ Havrix, by GlaxoSmithKline: adult and pediatric versions do not contain thimerosal. They contain 2-phenoxyethanol as a preservative.
- ❖ VAQTA, by Merck: contains no preservative.

Hepatitis B - Adults

- ❖ Recombivax, by Merck: only single dose vials for adult and dialysis use are available; none contain preservatives.
- ❖ Engerix, by GlaxoSmithKline: the adult version is formulated without preservatives. It contains a trace amount of mercury (less than 0.5 mcg) remaining from the manufacturing process.

Combination Vaccines

- ❖ Twinrix (Hep B-HIB), by GlaxoSmithKline: contains 2-phenoxyethanol as a preservative.
 - ❖ Contains a trace of thimerosal – less than 1 mcg mercury.

Pneumococcal – Adults, special child populations

- ❖ Pneumovax 23, by Merck: contains phenol as a preservative.

Meningococcus

- ❖ Menomune, by Aventis: available in preservative-free single dose vials
 - ❖ **Multi-dose vials containing thimerosal are also sold.**
 - ❖ **Used for adults and children ages 2 and up.**

Tetanus Toxoid and Tetanus Toxoid Adsorbed*

- ❖ Sole manufacturer: Aventis: both formulations contain 25 mcg mercury from thimerosal, although this product is only sold in single dose vials.
 - ❖ Package inserts available at http://www.vaccineshoppe.com/US_PDF/800-83_4258.pdf and http://www.vaccineshoppe.com/US_PDF/812-84_4252.pdf
 - ❖ For use in adults and children 7 years of age and older.

Tetanus and Diphtheria Toxoids*

- ❖ Sole manufacturer: Aventis: formulation contains 25 mcg of mercury.
 - ❖ For use in adults and children 7 years of age and older.

Influenza

- ❖ Flu Mist, by Wyeth: does not contain thimerosal.
 - ❖ Indicated for individuals age 5-49 years old.
- ❖ Fluzone, by Aventis: multidose vials and pre-filled syringes for adults contain thimerosal.

- ❖ Fluvirin, by Chiron: for adults and children age 4 years and older.
 - ❖ Contains 25 mcg mercury from thimerosal per dose.
 - ❖ See http://www.mmd.admin.state.mn.us/mmcap/pdf/flu_vaccine_insert.pdf

Rabies

- ❖ Imovax Rabies, by Aventis: available only in single dose vials containing no preservatives.
- ❖ Rabavert, by Chiron: sold in single dose vials and contains no preservative.

Monovalent Measles, Mumps, and Rubella

- ❖ Attenuvax (measles), Menvax (rubella), Mumsvax (mumps), by Merck: all are thimerosal-free or have undetectable amounts of thimerosal left from the manufacturing process.

Japanese Encephalitis*

- ❖ JE-VAX, by Aventis: this vaccine is only available in thimerosal-containing formulations.
 - ❖ Contains 35 mcg Hg per adult dose and 17.5 mcg Hg per pediatric dose (age 1-3 years).
 - See <http://www.fda.gov/cber/vaccine/thimerosal.htm#pres>

BCG

- ❖ TheraCys-BCG, by Aventis: does not contain preservatives.

Typhoid

- ❖ Typhim Vi, by Aventis: formulation contains phenol as a preservative, is thimerosal-free.
- ❖ Vivotif, by Berna: does not contain preservatives.

Yellow Fever

YF-VAX, by Aventis: contains no preservative.

- ❖ Package insert is available at http://www.vaccineshoppe.com/US_PDF/915-01_4283.pdf

Biologics

Per FDA, all immune globulins, including all Rho(D) immune globulins, are now thimerosal-free.
See --

<http://www.fda.gov/cber/vaccine/thimfaq.htm>

<http://www.fda.gov/cber/blood/mercplasma.htm>

*Trace information available at <http://www.fda.gov/cber/vaccine/thimerosal.htm#pres>